

**H**

Court of Appeals of South Carolina.

Monica WESTON, Appellant,

v.

KIM'S DOLLAR STORE and CIBA Vision, a division of Novartis Company, Respondents.

**No. 4592.**

Heard June 9, 2009.

Decided July 15, 2009.

Rehearing Denied Nov. 19, 2009.

**Background:** Contact lens purchaser filed suit against manufacturer of lenses, asserting negligence and strict liability claims, as well as breach of warranty claims, after she wore lenses, and developed an eye infection that led to temporary loss of vision in her eye. Manufacturer filed motion for summary judgment. The Circuit Court, Richland County, 2006 WL 4911566, G. Thomas Cooper, Jr., J., granted motion in part. Purchaser appealed.

**Holdings:** The Court of Appeals, Cureton, J., held that:

- (1) non-corrective, colored contact lenses with ultraviolet light (UV) protection were “medical devices,” subject to regulation by Food and Drug Administration (FDA), and
- (2) state claims against manufacturer that were dependent on warning, labeling, design, marketing, or misbranding of lenses were preempted by federal law.

Affirmed.

West Headnotes

**[1] States 360 ↪18.5**

360 States

360I Political Status and Relations

360I(B) Federal Supremacy; Preemption

360k18.5 k. Conflicting or conforming laws or regulations. **Most Cited Cases**

Any state law that conflicts with federal law is without effect. **U.S.C.A. Const. Art. 6, cl. 2.**

**[2] States 360 ↪18.13**

360 States

360I Political Status and Relations

360I(B) Federal Supremacy; Preemption

360k18.13 k. State police power. **Most Cited Cases**

In applying the Supremacy Clause, courts start with the assumption that the historic police powers of the states are not to be superseded by a federal act unless that was the clear and manifest purpose of congress. **U.S.C.A. Const. Art. 6, cl. 2.**

**[3] Statutes 361 ↪176**

361 Statutes

361VI Construction and Operation

361VI(A) General Rules of Construction

361k176 k. Judicial authority and duty. **Most Cited Cases**

The interpretation of a statute is a question of law for the court.

**[4] Courts 106 ↪4**

106 Courts

106I Nature, Extent, and Exercise of Jurisdiction in General

106k3 Jurisdiction of Cause of Action

106k4 k. In general. **Most Cited Cases**  
 “Subject matter jurisdiction” is the power of a court to hear and determine cases of the general class to which the proceedings in question belong.

**[5] Courts 106 ↪153**

106 Courts

106III Courts of General Original Jurisdiction

106III(B) Courts of Particular States

106k153 k. South Carolina. **Most Cited Cases**

Tort claims are within the jurisdiction of the circuit

court.

**[6] States 360** ⚙️18.11

360 States

360I Political Status and Relations

360I(B) Federal Supremacy; Preemption

360k18.11 k. Congressional intent. [Most](#)

[Cited Cases](#)

When federal law seats exclusive jurisdiction over a particular type of claim in the federal courts, state courts must examine the federal law to determine whether it preempts state law. [U.S.C.A. Const. Art. 6, cl. 2.](#)

**[7] States 360** ⚙️18.11

360 States

360I Political Status and Relations

360I(B) Federal Supremacy; Preemption

360k18.11 k. Congressional intent. [Most](#)

[Cited Cases](#)

Interpreting federal statutes is an essential step in determining whether federal law preempts state law. [U.S.C.A. Const. Art. 6, cl. 2.](#)

**[8] Judgment 228** ⚙️185(5)

228 Judgment

228V On Motion or Summary Proceeding

228k182 Motion or Other Application

228k185 Evidence in General

228k185(5) k. Weight and sufficiency.

[Most Cited Cases](#)

Generally, only a mere scintilla of evidence is required to defeat a motion for summary judgment when the burden of proof is by a preponderance of the evidence. [Rules Civ.Proc., Rule 56\(c\).](#)

**[9] Federal Civil Procedure 170A** ⚙️2546

170A Federal Civil Procedure

170AXVII Judgment

170AXVII(C) Summary Judgment

170AXVII(C)3 Proceedings

170Ak2542 Evidence

170Ak2546 k. Weight and suffi-

ciency. [Most Cited Cases](#)

In cases applying federal law, the non-moving party must submit more than a mere scintilla of evidence to withstand a motion for summary judgment. [Rules Civ.Proc., Rule 56\(c\).](#)

**[10] Products Liability 313A** ⚙️227

313A Products Liability

313AIII Particular Products

313Ak223 Health Care and Medical Products

313Ak227 k. Implants and prosthetic

devices. [Most Cited Cases](#)

**States 360** ⚙️18.65

360 States

360I Political Status and Relations

360I(B) Federal Supremacy; Preemption

360k18.65 k. Product safety; food and

drug laws. [Most Cited Cases](#)

Non-corrective colored contact lenses with ultraviolet light (UV) protection were “medical devices,” within meaning of Medical Device Amendments (MDA) of the Federal Food, Drug, and Cosmetic Act (FDCA), and, thus, were subject to regulation by the Food and Drug Administration (FDA) as a Class III medical device, for purposes of determining whether contact lens purchaser's state law claims against manufacturer of contact lenses that were dependent on warning, labeling, design, marketing, or misbranding were preempted by MDA; manufacturer had always treated lenses as medical devices, lenses had always been approved through FDA's premarket approval (PMA) process for Class III medical devices, and record was replete with evidence of lenses' medical, health, or therapeutic use and their physical or physiological effects, which required lenses to be regulated as medical devices. [U.S.C.A. Const. Art. 6, cl. 2;](#) [Federal Food, Drug, and Cosmetic Act, §§ 201\(h\), 521\(a\), 21 U.S.C.A. §§ 321\(h\), 360k\(a\); 21 C.F.R. § 700.3\(b\).](#)

**[11] Appeal and Error 30** ⚙️204(2)

30 Appeal and Error

30V Presentation and Reservation in Lower Court of Grounds of Review

30V(B) Objections and Motions, and Rulings Thereon

30k202 Evidence and Witnesses

30k204 Admission of Evidence

30k204(2) k. Nature of evidence in general. [Most Cited Cases](#)

Court of Appeals would not address on plaintiff's appeal of grant of summary judgment to defendant issue of whether testimony of defendant's representative was hearsay, as there was no evidence that plaintiff raised this argument to the trial court.

**[12] Products Liability 313A** 227

313A Products Liability

313AIII Particular Products

313Ak223 Health Care and Medical Products

313Ak227 k. Implants and prosthetic devices. [Most Cited Cases](#)

**States 360** 18.65

360 States


360I Political Status and Relations

360I(B) Federal Supremacy; Preemption

360k18.65 k. Product safety; food and drug laws. [Most Cited Cases](#)

Non-corrective, colored contact lens purchaser's state law claims against manufacturer of contact lenses that were Class III medical devices subject to premarket approval (PMA) process by Food and Drug Administration (FDA) that were dependent on warning, labeling, design, marketing, or misbranding of lenses, were preempted by Medical Device Amendments (MDA) of Federal Food, Drug, and Cosmetic Act (FDCA), as a jury's acceptance of disputed claims could result in different or additional requirements from the federal requirements, i.e., a jury could potentially find additional or different labeling was appropriate for the lenses, which would impermissibly affect model FDA had already approved. [U.S.C.A. Const. Art. 6, cl. 2](#); Federal Food, Drug, and Cosmetic Act §§ 201(h),

515, 521(a), [21 U.S.C.A. §§ 321\(h\)](#), [360e](#), [360k\(a\)](#); [21 C.F.R. § 700.3\(b\)](#).

**[13] States 360** 18.3


360 States

360I Political Status and Relations

360I(B) Federal Supremacy; Preemption

360k18.3 k. Preemption in general. [Most Cited Cases](#)

Whether a federal statute preempts state law is a question of law for the court to decide.


**[14] Health 198H** 107

198H Health

198HI Regulation in General

198HI(A) In General

198Hk107 k. Preemption. [Most Cited Cases](#)

**Products Liability 313A** 227

313A Products Liability

313AIII Particular Products

313Ak223 Health Care and Medical Products

313Ak227 k. Implants and prosthetic devices. [Most Cited Cases](#)

**States 360** 18.65

360 States

360I Political Status and Relations

360I(B) Federal Supremacy; Preemption

360k18.65 k. Product safety; food and drug laws. [Most Cited Cases](#)

Premarket approval (PMA) process of a medical device by the Food and Drug Administration (FDA) results in device-specific requirements that preempt inconsistent state requirements, including those sought to be imposed through tort liability. [U.S.C.A. Const. Art. 6, cl. 2](#); Federal Food, Drug, and Cosmetic Act, §§ 515, 521(a), [21 U.S.C.A. §§ 360e](#), [360k\(a\)](#).

**[15] Appeal and Error 30** 707(1)

## 30 Appeal and Error

## 30X Record

## 30X(M) Questions Presented for Review

## 30k707 Judgment

## 30k707(1) k. In general. Most Cited

## Cases

Court of Appeals was unable to review on appeal issue of whether trial court erred in refusing to amend or clarify certain provisions of its order granting partial summary judgment to defendant, as Court was unable to discern from record whether plaintiff raised this issue in trial court. [Appellate Court Rule 210\(h\)](#).

**\*\*771 Robert L. Widener, Celeste T. Jones, A. Victor Rawl, Jr., and Andrew G. Melling**, all of Columbia, for Appellant.

[Curtis L. Ott](#) and Daniel T. Sullivan, both of Columbia and [Keith D. Munson](#) and [Sandi R. Wilson](#), both of Greenville, for Respondents.

[CURETON, A.J.](#)

**\*523** Monica Weston appeals the circuit court's grant of summary judgment and dismissal of Counts II, V, and VI of her tort action against CIBA Vision (CIBA). On appeal, she argues the circuit court erred in granting summary judgment because (1) the circuit court lacked jurisdiction to determine whether the contact lenses at issue were federally regulated medical devices, (2) a genuine issue of material fact existed, and (3) there was neither a showing nor a finding that any South Carolina law conflicted with federal law. In addition, Weston argues the circuit court erred in refusing to amend or clarify certain provisions of its summary judgment order. We affirm.

**FACTS**

CIBA sells contact lenses under the trade name FreshLook Colors. FreshLook Colors contact lenses can be worn to change the color or appearance of the eye. These contact lenses, however, are also capable of correcting [nearsightedness](#), farsighted-

ness, and [astigmatism](#). FreshLook Colors contact lenses come in a range of powers from (-)20.00 diopters\***524** to (+)20.00 diopters. At the zero-power point in the range, the lenses are “non-corrective” or “plano” lenses, but the lenses can still have medical and physiological effects.

In March 2004, Weston purchased two pairs of FreshLook Colors contact lenses at the zero-power point from Kim's Dollar Store (Kim's).<sup>FN1</sup> Along with changing the eye color, the contact lenses Weston purchased had UV protection and were marked with a “prescription only” symbol. Kim's was not authorized to sell or distribute the contact lenses and had no affiliation with CIBA. Additionally, Weston did not have a prescription for the contact lenses. Weston was given no instructions concerning the care, cleaning, or usage of the lenses with her purchase, nor was she informed of the necessity of a medical prescription and oversight for usage of the contact lenses.

<sup>FN1</sup>. While Weston did not keep the actual pair of contacts she purchased or any of the packaging, both parties have stipulated the contacts involved were FreshLook Colors with ultraviolet (UV) protection, to be sold by prescription only, and approved for extended wear.

After wearing a pair of the FreshLook Colors contact lenses, Weston developed an [eye infection](#), which led to the temporary loss of vision in her left eye. Weston then brought this action against Kim's and CIBA alleging six causes of action: (1) negligence per se for selling misbranded contact lenses; (2) negligence in the manufacture, sale and/or distribution of contact lenses, and in failing to provide adequate warnings and instructions; (3) breach of implied warranty of merchantability and fitness because the lenses were not safely labeled; (4) strict liability for placing defectively labeled products into the stream of commerce; (5) sale of a defective product due to inadequate warnings; and (6) violation of the South Carolina Unfair Trade Practices Act by committing an unfair or deceptive act or

practice, including inadequate labeling and warnings, in the conduct of trade or commerce. CIBA's answer generally denied Weston's allegations and asserted additional defenses. CIBA also made a motion for summary judgment on the basis that the majority of Weston's claims and legal theories were subject to federal preemption pursuant to the Medical Device Amendments of 1976(MDA) to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. §§ 301-399a (West 1999 & Supp.2008) (FDCA).

\*525 Following a hearing on the matter, the circuit court granted CIBA's motion. The circuit court found CIBA was entitled to summary judgment on the basis of federal preemption on all actions dependent on warning, labeling, design, marketing, misbranding,\*\*772 or other similar claims. The circuit court also stated CIBA could file additional motions to test the viability of the remaining causes of action. Finally, the circuit court restricted Weston from pursuing any additional discovery, without further court order, on the issues of warnings, labeling, packaging, use instructions, product design, marketing, or illegal sales of contact lenses. This appeal follows.

#### STANDARD OF REVIEW

When reviewing the grant of a summary judgment motion, this court applies the same standard that governs the circuit court under Rule 56(c), SCRPC. *Englert, Inc. v. Netherlands Ins. Co.*, 315 S.C. 300, 302, 433 S.E.2d 871, 873 (Ct.App.1993). This standard requires all facts and reasonable inferences to be drawn therefrom to be viewed in the light most favorable to the appellant. *Id.* However, “[a]n appellate court may decide questions of law with no particular deference to the trial court.” *In re Campbell*, 379 S.C. 593, 599, 666 S.E.2d 908, 911 (2008)

#### LAW/ANALYSIS

Weston argues the circuit court erred in granting

summary judgment because (1) the circuit court lacked jurisdiction to determine whether the contact lenses at issue were federally regulated medical devices, (2) a genuine issue of material fact existed, and (3) there was neither a showing nor a finding that any South Carolina law conflicted with federal law. We disagree.

#### I. Preemption

[1][2] The Supremacy Clause of the United States Constitution provides that federal law “shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” U.S. Const. art. VI. Thus, as has been clear since the Supreme Court's decision in \*526M'Culloch v. Maryland, 17 U.S. (4 Wheat.), 316, 4 L.Ed. 579 (1819), any state law that conflicts with federal law is “without effect.” *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992) (citing *Maryland v. Louisiana*, 451 U.S. 725, 746, 101 S.Ct. 2114, 68 L.Ed.2d 576 (1981)).

In applying the Supremacy Clause, courts “start with the assumption that the historic police powers of the States [are] not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress.” *Medtronic v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)). Therefore, “ ‘[t]he purpose of Congress is the ultimate touchstone’ in every pre-emption case.” *Id.* (citing *Cipollone*, 505 U.S. at 516, 112 S.Ct. 2608, 120 L.Ed.2d 407).

*Jamison v. Ford Motor Co.*, 373 S.C. 248, 261-62, 644 S.E.2d 755, 762 (Ct.App.2007) (quoting *King v. Ford Motor Co.*, 209 F.3d 886, 891 (6th Cir.2000)).

[3] “The interpretation of a statute is a question of law for the [c]ourt.” *In re Campbell*, 379 S.C. 593,

599, 666 S.E.2d 908, 910-11 (2008); accord *Anderson v. Sara Lee Corp.*, 508 F.3d 181, 191 (4th Cir.2007) (holding whether federal statute preempts state law is a question of law). The MDA generally preempts state law that affects medical devices covered by the MDA unless an exemption is granted:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C.A. § 360k(a) (West 1999). Under the FDCA, a “device” is:

[A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is ... intended for use ... in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or \*527 ... intended to affect the structure or any \*\*773 function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C.A. § 321(h) (West 1999). A “cosmetic” is an article, or a component thereof, “intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance.”

21 U.S.C.A. § 321(i) (West 1999). Federal law contemplates that a regulated device may simultaneously be classified as a cosmetic. 21 C.F.R. §

700.3 (1981) (“Any cosmetic product which is also a drug or device or component thereof is also subject to the requirements of Chapter V [of the FDCA].”).

[4][5][6][7] Weston casts her argument as an attack on jurisdiction, presumably over the subject matter of her suit. Subject matter jurisdiction is “the power of a court to hear and determine cases of the general class to which the proceedings in question belong.” *McCullar v. Estate of Campbell*, 381 S.C. 205, 206, 672 S.E.2d 784, 784 (2009). Tort claims are within the jurisdiction of the circuit court. *Id.* When federal law seats exclusive jurisdiction over a particular type of claim in the federal courts, South Carolina courts must examine the federal law to determine whether it preempts state law. *Griggs v. S.C. Elec. & Gas Co.*, 320 S.C. 127, 129, 463 S.E.2d 608, 609 (1995). Weston appears to argue the circuit court was somehow deprived of the authority to determine whether federal law preempted state law while presumably retaining the authority to award Weston damages for her loss. This argument is meritless. Interpreting federal statutes is an essential step in determining whether federal law preempts state law. The question whether CIBA's FreshLook Colors contact lenses fit the statutory definition of medical devices, thus triggering the MDA's provision preempting state law, is properly a question of law for the circuit court. Consequently, the circuit court did not err in construing federal law to determine it preempted South Carolina law in this matter.

## \*528 II. Background: Federal Regulation of Contact Lenses

For regulation purposes, the Food and Drug Administration (FDA) classifies medical devices into three categories: Class I, Class II, and Class III. 21 U.S.C.A. § 360c (West 1999). The FDA applies different levels of scrutiny and regulation to each category in order to establish the safety and effectiveness of a medical device. *Id.* Class III medical devices receive the highest level of scrutiny and

may only be marketed pursuant to the FDA's pre-market approval (PMA) process. 21 U.S.C.A. § 360e (West 1999 & Supp.2008). The PMA process is rigorous, and it begins with the manufacturer of the medical device submitting detailed information to the FDA regarding the safety and efficacy of the device. *Riegel v. Medtronic*, 552 U.S. 312, ---, 128 S.Ct. 999, 1004, 169 L.Ed.2d 892 (2008). The FDA spends an average of one thousand, two hundred hours reviewing all of the submitted information and “grants [PMA] only if it finds there is a ‘reasonable assurance’ of the device's ‘safety and effectiveness.’ ” *Id.*

After a product receives PMA, “the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness.” *Id.* at 1005. If such changes are to be made, the manufacturer may submit a supplemental PMA application to the FDA, which is evaluated in a similar fashion as the initial application. *Id.* This supplemental PMA process obviates the need to submit redundant information to the FDA regarding design features, manufacturing processes, or labeling that have already been approved by the FDA, because the entirety of the PMA, including all supplements, are before the FDA at the time the supplement is reviewed. 51 Fed.Reg. 26,342, 26,354 (1986). Following PMA, the FDA continues to subject the medical devices to reporting requirements. *Riegel*, 128 S.Ct. at 1005.

According to the affidavit of CIBA's expert witness Philip Phillips, former Deputy Director for Science and Regulatory Policy in \*\*774 the Office of Device Evaluation for the FDA, all soft contact lenses automatically became Class III medical devices when the MDA was implemented in 1976. In 1994, the FDA drew a distinction between daily wear and extended wear soft contact lenses. Daily wear lenses were reclassified as Class II \*529 medical devices while extended wear lenses remained Class III medical devices. These classifications applied to both plano lenses and corrective lenses.

In 2003, the FDA issued Import Alert 86-10, which allowed for the possibility of obtaining cosmetic classification, under certain circumstances, for plano contact lenses intended solely for the decorative purpose of changing the eye color. With a cosmetic classification, the lenses could be sold without having to undergo the rigorous PMA process. If contact lenses were marketed with any claims of effecting physical or physiological changes, then even plano contact lenses that change the color of the eye would continue to be regulated as medical devices by the FDA. The Import Alert provided a claim of sunscreen protection as an example of a claim that would disqualify a product as a cosmetic. In 2005, Congress eliminated the carve-out set forth in Import Alert 86-10 by making all contact lenses, even solely decorative contact lenses, subject to regulation as medical devices by the FDA. 21 U.S.C.A. § 360j(n)(1) (West Supp.2008).

### III. Summary Judgment

Rule 56(c), SCRC, provides:

[Summary judgment] shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.

#### A. Genuine Issue of Material Fact

[8][9] “In determining whether any triable issue of fact exists, the evidence and all factual inferences drawn from it must be viewed in a light most favorable to the nonmoving party.” *Donahue v. Multimedia, Inc.*, 362 S.C. 331, 337, 608 S.E.2d 162, 165 (Ct.App.2005). This court, however, is not “required to single out some one morsel of evidence ... to create an issue of fact that is not genuine.” *Englert*, 315 S.C. at 302, 433 S.E.2d at 873 (quotations and citations omitted). Generally, only “a mere scintilla of evidence” is required to defeat a motion for summary judgment when the burden of

\*530 proof is by a preponderance of the evidence. *Hancock v. Mid-South Mgmt. Co.*, 381 S.C. 326, 330, 673 S.E.2d 801, 803 (2009). However, “in cases applying federal law, ... the non-moving party must submit more than a mere scintilla of evidence to withstand a motion for summary judgment.” *Id.* at 330-31, 673 S.E.2d at 803.

Weston asserts a genuine issue of material fact exists as to whether FreshLook Colors contact lenses were subject to regulation by the FDA as a Class III medical device. Specifically, Weston argues while PMA exists for all FreshLook Colors contact lenses with a diopter of greater or less than zero, the FreshLook Colors PMA excluded plano lenses because they have no effect on visual acuity. In support, Weston points to language in letters from the Department of Health and Human Services (DHHS) addressing a PMA supplement stating FreshLook Colors contact lenses were “indicated for the correction of visual acuity.” This indication, Weston reasons, excludes the lenses she purchased because, by definition, plano lenses do not correct vision. Furthermore, according to Weston, CIBA's marketing of the plano FreshLook Colors lenses for beautification rather than for correction of visual acuity invalidates any PMA that might have applied. We find this argument unpersuasive.

[10] Initially, we find FreshLook Colors contact lenses fit the FDCA's definition of a device, in that each lens is an “instrument ... or other similar or related article ... intended for use ... in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or ... intended to affect the structure or any function of the body of man...” 21 U.S.C.A. § 321(h). As CIBA points out, these lenses contain UV protection for the prevention of disease, and as extended-wear lenses, they affect the structure\*\*775 of the eye. Furthermore, we find CIBA presented uncontradicted competent evidence in the form of affidavits, depositions, and documentation, indicating FreshLook Colors contact lenses were Class III medical devices, subject to and approved by the FDA pursuant to the PMA pro-

cess.

Weston's expert witness, Dr. Suzanne Parisian, acknowledged the PMA history for FreshLook Colors contact lenses began with the original 1983 PMA. She further acknowledged \*531 through PMA Supplement 39 the FDA allowed FreshLook Colors UV to include the UV symbol on its labeling. CIBA then presented additional extensive evidence that through the supplemental PMA process the FreshLook Colors contact lenses in question received FDA approval through Supplement 39.

Two letters from the DHHS discussed Supplement 39. The first letter, dated January 25, 1996, referenced “P830037/S39 FreshLook Colors UV and FreshLook LiteTint UV.” This letter read:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your pre-market approval application (PMA) supplement, which requested approval for incorporating an ultra-violet absorber into the above referenced lenses. Based upon the information submitted, the PMA supplement is approved subject to the conditions described below and in the “Conditions of Approval” (enclosed). You may begin commercial distribution of the devices as modified by your PMA supplement upon receipt of this letter.

The second DHHS letter, dated August 22, 2003, referenced two PMA supplements, one being “P830037/S39 FreshLook Colors UV and FreshLook LiteTint UV (phemfilcon A) UV Soft (hydrophilic) Contact Lenses.” FN2 This letter stated:

FN2. The other PMA supplement referenced was “P830037/S46 FreshLook COLORBLENDS (phemfilcon A) UV Soft Contact Lenses.”

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) completed its evaluation of your pre-

market approval application (PMA) supplement[ ] referenced above and issued [an] approval order [ ] on ... January 25, 1996[,] for Supplement 39. We inadvertently made an error by not including the appropriate restricted device conditions of approval that apply to all UV absorbing contact lenses.

The letter went on to provide the restrictions and warnings that applied to the referenced contact lenses. However, despite the thoroughness with which the regulatory agencies reviewed CIBA's submissions, we find no indication in the record the DHHS or the FDA excluded any specific diopter or diopter range from the applicable PMA or its supplements. \*532 By contrast, both the regulatory agencies and CIBA treated the plano lenses no differently than their corrective counterparts. Plano lenses were included in the approved diopter range, were provided to the regulatory agencies as exemplars of the FreshLook Colors product, and were accompanied by all the same warnings, labels, and information as corrective FreshLook Colors lenses.

[11] In addition to this documentation, CIBA presented expert witnesses who confirmed the FreshLook Colors contact lenses in question were approved and regulated by the FDA. Paul Oris, Head of Global Regulatory Affairs for CIBA, testified at his deposition that CIBA always treated FreshLook lenses as medical devices and that they were always approved through the PMA process. FN3 \*\*776 He stated, "All [FreshLook Colors] contact lenses, including plano, were approved by the FDA in the PMA process." Oris also explained the "Rx only" symbol on the package of the contact lenses at issue indicated the contacts were medical devices that should only be sold by prescription. Oris further stated the package insert that was meant to accompany all FreshLook Colors contact lenses was drafted by CIBA pursuant to a PMA supplement.

FN3. In her brief, Weston argues Oris's testimony is hearsay. We find no evidence

of this argument being made to the circuit court, and therefore, we decline to address it. See *Wilder Corp. v. Wilke*, 330 S.C. 71, 76, 497 S.E.2d 731, 733 (1998) ("It is axiomatic that an issue cannot be raised for the first time on appeal, but must have been raised to and ruled upon by the [circuit court] to be preserved for appellate review."). We note CIBA's brief argues this issue was not properly preserved because it was raised to the circuit court for the first time in a Rule 59(e) motion, and hearsay objections cannot be raised for the first time on appeal. However, after reviewing the record we are unable to find the Rule 59(e) motion to which CIBA refers, so without a complete record for review, we need not reach CIBA's argument. See Rule 210(h), SCACR ("[T]he appellate court will not consider any fact which does not appear in the Record on Appeal.").

CIBA's expert witness Phillips confirmed in his deposition that the package insert that was to be included with all FreshLook Colors contact lenses was reviewed and approved by the FDA. Phillips stated the package insert that was submitted and approved by the FDA as part of the FDA's PMA oversight function was "probably what [the] FDA looked at closer than any other aspect of labeling." He further \*533 stated this FDA-approved insert applied to the specific contact lenses at issue.

Phillips provided further support that FreshLook Colors contact lenses were approved and regulated by the FDA and were unaffected by Import Alert 86-10 in his affidavit, which asserted:

FreshLook Colors Lenses of the type [at issue] are Class III medical devices. This would include plano (zero power) FreshLook Colors lenses in 2004.... FreshLook Colors plano (zero power) contact lenses are approved in the Premarket Approval (PMA) P830037 and the relevant supplements thereto.... CIBA [s] ... PMA approval was in accord with all applicable FDA requirements

and resulted in legitimate approval of CIBA Vision FreshLook Colors contact lenses as Class III medical devices.... In PMA Supplement 33, [CIBA] obtained approval from the FDA to incorporate the UV absorber ingredient into FreshLook Colors lenses. As of at least July 2003, the FDA approved [CIBA] package insert for FreshLook Colors lenses included significant information about UV absorbing properties and UV protection.... UV protection[ ] would constitute a “medical use” under Import Alert 86-10 and therefore further make FreshLook Colors plano lenses ineligible for regulation as a “cosmetic.” ... [CIBA's] packaging, product information, warnings and labeling for FreshLook Colors contact lenses [ ] were in accordance with the FDA's PMA and PMA Supplement approvals and the agency's labeling regulation.... Throughout 2004, [CIBA] compliance with the Conditions of Approval, good manufacturing practices, medical device reporting requirements and other requirements reviewed by FDA were sufficient to maintain the PMA approval status for FreshLook Colors contact lenses.

Furthermore, the record contains ample discussion and evidence on the distinction between a cosmetic and a medical device. When discussing whether plano color contact lenses used to enhance the color of the eye are currently considered cosmetics, as the exception in Import Alert 86-10 had provided, Dr. Parisian explained, “Just because [the FDA] put [the lenses] under the device regulations doesn't change that [the lenses are] still a cosmetic.... [The lenses are] a cosmetic, \*534 but [they are] being regulated under medical device regulation.” When asked whether the FDA would consider plano color contact lenses intended to enhance the color of the eye for extended wear to be medical devices, Dr. Parisian stated, “[The FDA] could, depending on the [manufacturer's] claims.”

This notion of plano color contact lenses being both a cosmetic and a medical device was in complete accord with the evidence presented by CIBA and

with federal law. Phillips explained in both his deposition and his affidavit that classification as a cosmetic and a medical device was not mutually exclusive. Further, CIBA presented the circuit court with a notice published in the Federal Register noting, “[The] FDA regulates as devices noncorrective tinted contact lenses that are expressly promoted only for their cosmetic effect of enhancing eye color because they have physiological effects on the eye.” 60 Fed.Reg. 41,453 (1995).

Moreover, while Weston presented much discussion regarding the cosmetic purposes of FreshLook Colors contact lenses, the record was also replete with evidence of their medical, health, or therapeutic use and their \*\*777 physical or physiological effects, which requires the lenses to be regulated as medical devices. See 21 C.F.R. § 700.3(b) (“Any cosmetic product which is also a drug or device or component thereof is also subject to the requirements of Chapter V of the [FDCA].”). Although Kim's did not provide Weston with the package insert intended to accompany the FreshLook Colors contact lenses she purchased, the lenses did have an applicable package insert that was in accord with FDA requirements and obtained FDA approval. This insert included the following “Indications (Uses)” for the lenses: “FreshLook soft contact lenses with UV-absorbing monomer help protect against transmission of harmful UV radiation to the cornea and into the eye,” and “The lenses may be prescribed for Daily Wear or Extended Wear....” The insert goes on to note, “Long term exposure to UV radiation is one of the risk factors associated with cataracts.... UV-absorbing contact lenses help provide protection against harmful UV radiation.”

This FDA approved language in the package insert clearly conveys the FreshLook Colors contact lenses in question had medical or therapeutic purposes and physiological effects on \*535 the eye, thus making the lenses medical devices. See 21 U.S.C.A. § 321(h) (“The term ‘device’ ... means an instrument, apparatus, implement, ... or other similar or related article, ... which is ... intended for use

... in the cure, mitigation, treatment, or prevention of disease, ... or intended to affect the structure or any function of the body....”). Weston's own expert witness did not contradict this conclusion. Dr. Parisian noted the UV symbol on the contact lenses' package and the PMA supplement information established the lenses in question contained a product to help block UV rays from the sun that can be harmful to the human eye. Dr. Parisian also acknowledged that when contact lenses are marketed “for extended wear, then it's a Class III [medical device].”

While these stated uses and warnings contained on both the packaging and package insert of FreshLook Colors contact lenses classify the lenses as medical devices subject to the MDA, they also indicate Import Alert 86-10's inapplicability to the contact lenses. Import Alert 86-10 stated it applied to color contact lenses “[p]rovided they are not marketed with claims that they effect physical or physiological change.... [Import Alert 86-10] does not cover contact lenses that are intended for ... medical or therapeutic use and that are, therefore, properly regulated as medical devices under the [FDCA].” The evidence demonstrates the FreshLook Colors contact lenses in question effect physiological changes and have medical or therapeutic uses, resulting in no change of classification following Import Alert 86-10.

After reviewing the documents, depositions, affidavits, and all other evidence in the record, we find CIBA carried its burden of demonstrating no genuine issue of material fact existed as to whether FreshLook Colors contact lenses of all diopeters underwent the rigorous PMA process and were, therefore, subject to regulation by the FDA. See *Englert*, 315 S.C. at 302, 433 S.E.2d at 873 (stating this court views all facts and reasonable inferences in light most favorable to appellant but is not “required to single out some one morsel of evidence ... to create an issue of fact that is not genuine”); see generally *Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 653, 93 S.Ct. 2488, 37 L.Ed.2d

235 (1973) (explaining the FDA \*536 has jurisdiction to decide the status or class of a medical product).

## B. Judgment as a Matter of Law

[12][13][14] Having reached this conclusion, we must address the issue of whether Weston's claims are subject to federal preemption, thereby entitling CIBA to judgment as a matter of law. See 21 U.S.C.A. § 360k(a) (explaining the MDA expressly preempts certain state law requirements governing medical devices); *Quigley v. Rider*, 357 S.C. 477, 483, 593 S.E.2d 476, 479 (Ct.App.2003) (explaining when state law and federal law conflict, the former must give way). Whether a federal statute preempts state law is a question of law for the court to decide. See *Campbell*, 379 S.C. at 599, 666 S.E.2d at 910-11; accord *Anderson*, 508 F.3d at 191. PMA approval of a medical device by the FDA results in device-specific requirements that preempt inconsistent state requirements, including \*\*778 those sought to be imposed through tort liability. *Riegel*, 128 S.Ct. at 1007-08; *Horn v. Thoratec Corp.*, 376 F.3d 163, 169 (3rd Cir.2004); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 584 (5th Cir.2001). Specifically, the MDA prohibits States from imposing on devices intended for human use “any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.” 21 U.S.C.A. § 360k(a). This preemption clause has been read to extend to state tort claims. *Riegel*, 128 S.Ct. at 1008.

The United States Supreme Court recently held “common-law causes of action for negligence and strict liability do impose ‘requirement[s]’ and would be pre-empted by federal requirements specific to a medical device.” *Id.* at 1007. The Supreme Court stated, “Absent other indication, reference to a State's ‘requirements’ includes its common-law duties.” *Id.* at 1008. The Supreme Court

reasoned:

[C]ommon-law liability is “premised on the existence of a legal duty,” and a tort judgment therefore establishes that the defendant has violated a state-law obligation.... And while the common-law remedy is limited to damages, a \*537 liability award “can be, indeed is designed to be, a potent method of governing conduct and controlling policy.”

*Id.* (internal quotations and citations omitted). Further, the Supreme Court agreed that “it is implausible that the MDA was meant to ‘grant greater power (to set state standards different from, or in addition to federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes.’ ” FN4  
*Id.* (internal quotations and citations omitted).

FN4. By contrast, in March 2009, the United States Supreme Court held federal law does not preempt state tort claims for injuries resulting from inadequate warning labels on prescription medications. *Wyeth v. Levine*, --- U.S. ----, ----, 129 S.Ct. 1187, 1201, 173 L.Ed.2d 51 (2009).

In the present case, the circuit court correctly applied the doctrine of federal preemption because a jury’s acceptance of the disputed claims could result in different or additional requirements from the federal requirements. A jury could potentially find additional or different labeling is appropriate for the FreshLook Colors contact lenses, which would affect the model the FDA has already approved. This is not permissible. *See id.* (“State tort law that requires a manufacturer’s catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect.”). Additionally, the United States District Court for the District of South Carolina has stated that “any cause of action based on testing, labeling or marketing is preempted by the FDA standards for premarket approval.” *Tarallo v. Searle Pharm., Inc.*, 704 F.Supp.

653, 656 (D.S.C.1988). Further, that court has found the MDA, “which expressly precludes the individual states from establishing requirements different from or in addition to those promulgated by the FDA, reveals on its face the congressional objective to prohibit, by the doctrine of express preemption, the proliferation of multiple, diverse, state by state device requirements.” *Stewart v. Int’l Playtex, Inc.*, 672 F.Supp. 907, 909 (D.S.C.1987) (emphasis in original).

Any state requirements imposed by a jury verdict in favor of the causes of action at issue would be in addition to or in contradiction of federal requirements, and therefore, Weston’s causes of action under South Carolina law are preempted and \*538 were properly dismissed by the circuit court. After carrying its burden of proving FreshLook Colors contact lenses were regulated by the FDA as Class III medical devices, CIBA then demonstrated it was entitled to judgment as a matter of law based on the doctrine of federal preemption. Consequently, the circuit court correctly granted summary judgment on all actions dependent on warning, labeling, design, marketing, misbranding, or other similar claims. *See Donahue*, 362 S.C. at 337, 608 S.E.2d at 165 (“Summary judgment is proper only when there is no genuine issue as to any material fact and the \*\*779 moving party is entitled to judgment as a matter of law.”).

#### IV. Remaining Issue

[15] Finally, Weston argues the circuit court erred in refusing to amend or clarify certain provisions of its order granting partial summary judgment. We do not reach this argument because we are unable to discern whether Weston raised to the circuit court the issues she now appeals. An appellate court’s review is limited to facts appearing in the record. Rule 210(h), SCACR. Weston’s February 2007 motion seeking amendment or clarification of the circuit court’s order granting partial summary judgment does not appear in the record. Consequently, we are unable to review the circuit court’s denial of

that motion.

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### CONCLUSION

As to whether the circuit court erred in granting summary judgment because it lacked jurisdiction to determine whether the contact lenses at issue were federally regulated medical devices, we find the circuit court properly interpreted federal statutes to determine whether the MDA preempted South Carolina law in this matter. Accordingly, we affirm the decision of the circuit court on this issue.

Regarding whether the circuit court erred in granting summary judgment because a genuine issue of material fact existed, we find the circuit court correctly concluded no genuine issue existed as to whether CIBA's FreshLook Colors contact lenses were federally regulated as medical devices. Therefore, we affirm the decision of the circuit court on this issue.

**\*539** As to whether the circuit court erred in granting summary judgment because there was neither a showing nor a finding that any South Carolina law conflicted with federal law, we find any jury verdict imposing different requirements than the federal law would constitute an impermissible conflicting state law. Consequently, we affirm the decision of the circuit court on this issue.

We do not reach the issue of whether the circuit court erred in refusing to amend or clarify certain provisions of its summary judgment order because the motion underlying this issue does not appear in the record.

Accordingly, the order of the circuit court is

**AFFIRMED.**

**HUFF** and **KONDUROS, JJ.**, concur.  
S.C.App.,2009.  
Weston v. Kim's Dollar Store  
385 S.C. 520, 684 S.E.2d 769