

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022388Orig1s000

OTHER REVIEW(S)

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion

*****Pre-decisional Agency Information*****

Memorandum

Date: February 11, 2022

To: Ahmed Ayodeji
Division of Ophthalmology (DO)

From: Carrie Newcomer, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Jim Dvorsky, Team Leader, OPDP

Subject: ACUVUE® THERAVISION™ WITH KETOTIFEN (etafilcon A drug-eluting contact lens with ketotifen), for ophthalmic use

NDA: 022388

In response to the Division of Ophthalmology (DO) consult request dated June 10, 2021, OPDP has reviewed the proposed product labeling (PI), carton and container labeling, Patient Instruction Guide, and Fitting Instruction Guide for the original NDA submission for ACUVUE® THERAVISION™ WITH KETOTIFEN (etafilcon A drug-eluting contact lens with ketotifen), for ophthalmic use.

Labeling: OPDP's comments on the proposed labeling are based on the draft labeling received by electronic mail from DO on January 27, 2022 and are provided below.

Carton and Container Labeling: OPDP has reviewed the attached proposed carton and container labeling received by electronic email from DO on January 27, 2022 and are provided below.

Thank you for your consult. If you have any questions, please contact Carrie Newcomer at (301) 796-1233 or Carrie.Newcomer@fda.hhs.gov.

51 Pages of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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/s/

CARRIE A NEWCOMER
02/11/2022 11:43:41 AM

USABILITY ASSESSMENT AND LABEL AND LABELING REVIEW
Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

*** This document contains proprietary information that cannot be released to the public***

Date of This Review:	December 2, 2021
Requesting Office or Division:	Division of Ophthalmology (DO)
Application Type and Number:	NDA 022388
Product Name and Strength:	Acuvue Theravision with Ketotifen (etafilcon A contact lens with ketotifen) Contact Lenses, 0.019 mg ketotifen per contact lens
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Johnson & Johnson Vision Care, Inc (JJVC)
FDA Received Date:	April 30, 2021 and June 1, 2021
OSE RCM #:	2021-906 and 2021-905
DMEPA 1 Safety Evaluator:	Deborah Myers, RPh, MBA
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD
DMEPA 1 Human Factors Associate Director:	Jason Flint, MBA, PMP

1 REASON FOR REVIEW

As part of the approval process for Acuvue Theravision with Ketotifen (etafilcon A contact lens with ketotifen) Contact Lenses, the Division of Ophthalmology (DO) requested that we review the proposed Acuvue Theravision with Ketotifen prescribing information (PI) patient instruction guide, fitting instructions guide (FIG), container label, and carton labeling for areas of vulnerability that may lead to medication errors. Additionally, we evaluated the usability assessment to determine whether the Applicant needs to submit the results of a human factors (HF) validation study as part of their NDA.

This is combination product with a proposed contact lens device constituent part for optical correction of refractive ametropia (myopia and hyperopia) (b) (4) who may have up to 1.00D of astigmatism.

1.1 PRODUCT DESCRIPTION

As described in the Usability Assessment, Acuvue Theravision with Ketotifen, is a combination product comprised of the device (contact lens) for optical correction of refractive ametropia (myopia and hyperopia) (b) (4) have up to 1.00D of astigmatism and the drug compartment, ketotifen, an H₁ histamine receptor antagonist indicated for preventing itching associated with allergic conjunctivitis. The contact lens is placed on the cornea of the eye, which corrects the refractive error by altering the direction of light rays to focus light properly onto the retina. Pictorial representations of the combination product interfaces are shown below (Fig 1a through 1d). Table 4 in Appendix A contains additional product details.



The proposed product is intended for contact lens wearers that are seasonal and perennial ocular allergy sufferers.

The intended use-environment is a healthy environment free from contamination and should not be used during activities involving water.

1.2 BACKGROUND

NDA 022388 is a 505(b)(2) NDA and the reference product is Zaditor (ketotifen fumarate) ophthalmic solution, 0.025% (NDA 021066).

2 MATERIALS REVIEWED

Table 1. Materials Considered for this Label and Labeling Review	
Material Reviewed	Appendix Section (for Methods and Results)
Product Information/Prescribing Information	A
Previous DMEPA Reviews	B
ISMP Newsletters*	C – N/A
FDA Adverse Event Reporting System (FAERS)*	D – N/A
Usability Assessment	E
Label and Labeling	F

N/A=not applicable for this review

*We do not typically search FAERS or ISMP Newsletters for our label and labeling reviews unless we are aware of medication errors through our routine postmarket safety surveillance

3 REVIEW OF USABILITY STUDY REPORT & ASSESSMENT

We note the Applicant submitted summary reports of labeling differentiation, product differentiation, and simulated use summative testing. Based on our evaluation of the user interface and considering other marketed contact lens products with similar use steps, we determined that the proposed product is low risk and human factors data is not needed to support this NDA. Additionally, we conducted a high level review of the submitted human factors summary reports and did not identify any use errors or difficulties of concern.

4 CONCLUSION AND RECOMMENDATIONS

The proposed prescribing information (PI) patient instruction guide, fitting instructions guide (FIG), container label, and carton labeling may be improved to promote the safe use of this product from a medication error perspective. We provide the identified medication error issues, our rationale for concern, and our proposed recommendations to minimize the risk for medication error in Section 5 for the Division and in Section 6 for Johnson & Johnson Vision Care, Inc.

5 RECOMMENDATIONS FOR DIVISION OF OPHTHALMOLOGY (DO)

Table 2. Identified Issues and Recommendations for Division of Ophthalmology (DO)		
IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
Highlights of Prescribing Information		
1. As currently presented under “Indications and Usage” we note the use of the population description as (b) (4) (b) (4) which could be confusing.	(b) (4) However, the statement could be misinterpreted (b) (4)	We recommend revising the text (b) (4) to (b) (4) and to provide further clarity revising the subsequent text (b) (4) We recommend the above changes also be implemented in Section 1, <i>Indication and Usage</i> , in the Full Prescribing Information.
Full Prescribing Information – Section 2 <i>Dosage and Administration</i>		
1. As currently presented, the fifth bullet point text begins with a negative statement, (b) (4)	We have received post-marketing reports that negative statements (e.g., do not) may have the opposite of the intended meaning because the word “not” can be overlooked and misinterpret the warning as an affirmative action. ^a Negative statements such as (b) (4)	To provide clarity we recommend revising the negative statement (b) (4) to “Avoid use of contact lens cleansing and disinfectant solutions. Discard lens after a single day’s use.”

^a Institute for Safe Medication Practices. Affirmative warnings (do this) may be better understood than negative warnings (do not do that). ISMP Med Saf Alert Acute Care. 2010;15(16):1-3.

Table 2. Identified Issues and Recommendations for Division of Ophthalmology (DO)

	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
		in the opposite of its intended effect, as the word "not" can be overlooked and inadvertently encourage the unintended action (e.g., cleaning or disinfecting the lens) resulting in wrong technique medication errors. However, using an affirmative statement will help ensure that end users understand the intent to discard the lens after a single day's use, even if they do not read every word.	
Full Prescribing Information – Section 16 <i>How Supplied/Storage and Handling</i>			
1.	As currently presented in subsection 16.2 <i>Storage and Handling</i>, the storage statement "Store at 15-25°C (59-77°F); (b) (4) lacks the degree symbol (°) and units of measurement (Centigrade and Fahrenheit respectively) following the first numbers in the temperature ranges.	The lower temperatures in the ranges may be overlooked. Additionally, when a hyphen is included in a range instead of the word "to," the hyphen can be overlooked.	To provide clarity, add the degree and Centigrade symbols (°C) following the number "15," and the degree and Fahrenheit symbols (°F) following the number "59" within the storage statement. Additionally, we also recommend replacing the hyphen with its intended meaning "to." For example, "Store at 15°C to 25°C (59°F to 77°F); (b) (4) ."

Table 2. Identified Issues and Recommendations for Division of Ophthalmology (DO)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
2.	As currently presented, the National Drug Code (NDC) is not included.	To facilitate identification of the dosage form, the NDC number is required per 21 CFR 201.57(c)(17)(iii).	Once assigned and in accordance with 21 CFR 201.57(c)(17)(iii), add the NDC number to the How Supplied section.
3.	As currently presented, the package configuration (i.e., carton containing 30 contact lenses) is not included.	The “units in which the dosage form is ordinarily available for prescribing by practitioners” is required by 21 CFR 201.57(c)(17)(ii).	Add the proposed package configuration (i.e., carton containing 30 contact lenses).
4.	As currently presented, the final sentence under subsection 16.1 <i>How Supplied</i> is “The plastic package is marked with base curve, lens diameter, diopter (lens power), date of manufacture, expiration date, and lot number.” However, the statement does not clarify that the “date of manufacture” is also included on the proposed container label.	Multiple dates are included on the label, thus clarifying what each date represents will help to minimize confusion.	We recommend including “date of manufacture” in the final sentence under subsection 16.1 <i>How Supplied</i> . Additionally, for further consistency we recommend reorganizing the labeling “variables” (i.e., base curve, lens diameter, diopter (lens power), date of manufacture, expiration date, and lot number) to align with the order of their inclusion on the proposed container label. For example, “The plastic package is marked with base curve, lens diameter, diopter (lens power), date of manufacture, expiration date, and lot number.”

6 RECOMMENDATIONS FOR JOHNSON & JOHNSON VISION CARE, INC

Table 3. Identified Issues and Recommendations for Johnson & Johnson Vision Care, Inc (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
Container Label and Carton Labeling			

Table 3. Identified Issues and Recommendations for Johnson & Johnson Vision Care, Inc (entire table to be conveyed to Applicant)

	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
1.	As currently presented, the "Recommended Dosage" statement is not included on the container label or carton labeling.	Per 21 CFR 201.55, "...labels for prescription drugs bear a statement of the recommended or usual dosage."	Add your intended "Recommended Dosage" statement. For example, "Dosage: Insert one lens per eye per day." or "Dosage: See prescribing information."
Carton Labeling			
1.	As currently presented, the storage statement is missing from the carton labeling.	The proposed prescribing information indicates to "Store at 15°C-25°C (59°F-77°F); [REDACTED] (b) (4) [REDACTED] Protect from light – store lenses in carton until use." Improper storage and handling may result in use of deteriorated drug medication errors.	To reduce the risk for deteriorated drug medication errors, add the storage statement to the carton labeling.
2.	As currently presented, the modifier portion of the proprietary name, "Theravision with Ketotifen," does not appear prominently on the carton labeling and could be missed. The modifier appears in a smaller font than the root name. Additionally, the modifier appears in the same green color as the green background color.	Overlooking the modifier could result in product selection errors, for example, an individual receiving Acuvue without Ketotifen, or vice versa.	Revise the appearance of the modifier to be commensurate to the appearance of the root name, Acuvue. Additionally, increase the prominence of the modifier, for example, through use of a contrasting color to the background colors on the carton labeling.
3.	As currently presented, the strength statement "0.019 mg per lens" is	Relocating the strength to appear in close proximity to the active ingredient for	To minimize the risk of confusion, we recommend relocating the strength

Table 3. Identified Issues and Recommendations for Johnson & Johnson Vision Care, Inc
(entire table to be conveyed to Applicant)

	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
	located on the upper right side of the principal display panel (PDP) away from the active ingredient may lead to confusion.	which it corresponds will help to provide clarity that the strength statement "0.019 mg per lens" is associated with the active ingredient, ketotifen.	statement "0.019 mg per lens" to a separate line, immediately following the established name and dosage form, "etafilcon A contact lens with ketotifen" on the PDP. This presentation would be similar to that on your proposed container label. For example: ACUVUE Theravision with Ketotifen (etafilcon A lens with ketotifen) 0.019 mg per lens

APPENDICES: METHODS & RESULTS FOR EACH MATERIAL REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table 4 presents relevant product information for Acuvue Theravision with Ketotifen that Johnson & Johnson Vision Care, Inc submitted on June 1, 2021, and the reference product (RP), Zaditor.

Table 4. Relevant Product Information for Acuvue Theravision with Ketotifen and the Reference Product, Zaditor		
Product Name	Acuvue Theravision with Ketotifen	Zaditor (NDA 021066) ^{b,c}
Initial Approval Date	N/A	July 2, 1999 (Rx) October 19, 2006 (OTC*)
Active Ingredient	ketotifen	ketotifen fumarate
Indication	(b) (4) Daily disposable contact lens for correcting refractive ametropia (myopia and hyperopia) in phakic or aphakic patients who are suitable for contact lens wear and experience ocular allergic itch due to allergic conjunctivitis and who do not have red eye(s) or more than 1.00 D of astigmatism.	For the temporary prevention of itching of the eye due to allergic conjunctivitis *Use: Temporarily relieves itchy eyes due to pollen, ragweed, grass, animal hair and dander.
Route of Administration	ophthalmic	Ophthalmic *Only for use in the eye
Dosage Form	Contact lenses	ophthalmic solution *eye drops
Strength	0.019 mg ketotifen per contact lens	0.025% *ketotifen 0.025% (equivalent to ketotifen fumarate 0.035%)
Dose and Frequency	Insert one contact lens per eye per day.	One drop in the affected eye(s) twice daily, every 8 to 12 hours.

^b Zaditor (Rx Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. July 2001. [cited 2021 DEC 01]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2001/21066s4lbl.pdf.

^c Zaditor [OTC Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. May 2012. [cited 2021 DEC 01]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021066Orig1s018lbl.pdf.

	• No more than one Acuvue Theravision with Ketotifen per eye per day should be used. • If prevention or relief of itching is needed beyond 12 hours, remove Acuvue Theravision with Ketotifen and consult your eye care professional. • Acuvue Theravision with Ketotifen may be worn beyond 12 hours for vision correction. Lenses should be removed prior to sleeping. • This lens is not intended to be cleaned or disinfected and should be discarded after a single day's use.	*Directions: Adults and children 3 years of age and older: Put 1 drop in the affected eye(s) twice daily, every 8-12 hours, no more than twice per day.
How Supplied	Each contact lens is supplied in a foil-sealed plastic package containing a buffered ketotifen solution. The plastic package is marked with base curve, diopter power, diameter, lot number and expiration date.	5 mL in bottle with controlled plastic dropped tip and white plastic cap.
Storage	Store at 15-25°C (59-77°F); (b) (4) Protect from light – store lenses in carton until use.	Store at 4° - 25°C (39° - 77°F).

APPENDIX B. PREVIOUS DMEPA REVIEWS

On October 1, 2021, we searched for previous DMEPA reviews relevant to this current review using the terms, "Acuvue" and "NDA 022388." Our search identified five previous reviews^{d,e,f,g,h}, and we considered our previous recommendations to see if they are applicable for this current review. We confirmed that our previous recommendations were implemented or are not applicable to this current review.

^d Myers, D. Proprietary Name Review for Acuvue Theravision with Ketotifen (NDA 022388). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2021 AUG 23. RCM No.: 2021-1044723992.

^e Kolejian, S. Proprietary Name Review for Acuvue Theravision with Ketotifen (IND 066883). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 DEC 15. RCM No.: 2017-16035909.

^f Abdus-Samad, J. Proprietary Name Review for [REDACTED] ^{(b) (4)} (IND 066883). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2011 MAR 25. RCM No.: 2010-2146.

^g Abdus-Samad, J. Proprietary Name Review for [REDACTED] ^{(b) (4)} (IND 066883). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2010 MAR 01. RCM No.: 2009-1674.

^h Abdus-Samad, J. Proprietary Name Review for [REDACTED] ^{(b) (4)} (IND 066883). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2010 FEB 24. RCM No.: 2010-430.

APPENDIX E. USABILITY ASSESSMENT

The Usability Assessment, received April 30, 2021, available from the following link:
<\\CDSESUB1\evsprod\nda022388\0001\m1\us\usablility-assessment.pdf>.

The Usability Study Report, received April 30, 2021, available from the following link:
<\\CDSESUB1\evsprod\nda022388\0001\m1\us\usablility-study-report.pdf>.

APPENDIX F. LABEL AND LABELING

F.1 List of Label and Labeling Reviewed

Using the principles of human factors and Failure Mode and Effects Analysis,¹ along with postmarket medication error data, we reviewed the following Acuvue Theravision with Ketotifen labels and labeling submitted by Johnson & Johnson Vision Care, Inc

- Container label received on April 30, 2021
- Carton labeling received on April 30, 2021
- Patient Instruction Guide (Instructions for Use (IFU)) (Image not shown) received on April 30, 2021:
 - Clean proposed (Draft) Patient Instruction Guide available from the following link: <\\CDSESUB1\evsprod\nda022388\0001\m1\us\draft-labeling-patient-instruction-guide-clean.doc>.
 - Annotated Patient Instruction Guide available from the following link: <\\CDSESUB1\evsprod\nda022388\0001\m1\us\annotated-draft-patient-instruction-guide.doc>.
- Fitting Instructions Guide (FIG) (Image not shown) received on June 1, 2021:
 - Clean proposed (Draft) FIG available from the following link: <\\CDSESUB1\evsprod\nda022388\0005\m1\us\draft-labeling-text-fig-clean.docx>.
 - Annotated FIG available from the following link: <\\CDSESUB1\evsprod\nda022388\0005\m1\us\annotated-draft-labeling-text-fig.docx>.
- Prescribing Information (PI) (Image not shown) received on June 1, 2021:
 - Clean proposed (Draft) PI available from the following link: <\\CDSESUB1\evsprod\nda022388\0005\m1\us\draft-labeling-text-pi-clean.docx>.
 - Annotated PI available from the following link: <\\CDSESUB1\evsprod\nda022388\0005\m1\us\annotated-draft-labeling-text-pi.docx>.

¹ Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

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/s/

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12/02/2021 11:20:18 AM

JASON A FLINT
12/02/2021 01:57:13 PM



NDA Clinical Review Memo

From: CAPT Kimberly Lewandowski-Walker, O.D., M.S., FAAO
Office of Regulatory Programs/Division 2/Regulatory Inspections and
Audits Team/MDSAP
Office of Product Evaluation and Quality

To: Dr. William Boyd, Lead Reviewer
CDER/OND/OSM/DO

CC: J. Angelo Green, Ph.D., DABT
Assistant Director
Contact Lenses and Dry Eye Devices Team
DHT1A: Division of Ophthalmic Devices | OHT1: Office of Ophthalmic,
Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality

Subject: NDA 022338– etafilcon A with ketotifen soft hydrophilic contact lens (K-Lens)

Sponsor: Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Suite 100
Jacksonville, FL 32256

Date: 2021-AUG-16

SUMMARY

The Sponsor has submitted a New Drug Application (NDA) for their soft hydrophilic contact lens consisting of etafilcon A with ketotifen (K-Lens). This device is a combination product with CDER as the lead Center. The device is intended for phakic and aphakic patients who are suitable for contact lens wear and experience ocular allergic itch due to allergic conjunctivitis and who do not have red eye(s) or more than 1.00 D of astigmatism.

A Sponsor meeting was held with representatives from CDER and the Sponsor on February 17, 2021 regarding the K-Lens under IND 66883. The submission of IND 66883 preceded the submission of NDA 022338. I (Kimberly Lewandowski-Walker) reviewed the device as it pertains to device regulations per IND 66883 and represented CDRH during the Sponsor call.

The draft labeling submitted by the sponsor for this device under NDA 022338 was reviewed by CAPT Kimberly Lewandowski-Walker. One (1) deficiency was noted, which is detailed in this memorandum.

DEVICE DESCRIPTION

The device is a daily wear, daily disposable soft hydrophilic contact lens consisting of etafilcon A with ketotifen. The device component of K-Lens is the etafilcon A (FDA Group IV), soft hydrophilic daily disposable contact lens. Etafilcon A is a copolymer of 2-hydroxyethyl methacrylate and methacrylic acid cross linked with 1,1,1-trimethylol propane trimethacrylate and ethylene glycol dimethacrylate. The lenses are tinted with (b) (4) to improve visibility and handling. (b) (4)

INTENDED USE

The proposed indication for K-Lens is as a daily disposable contact lens for correcting refractive ametropia (myopia and hyperopia) in phakic or aphakic patients who are suitable for contact lens wear and experience ocular allergic itch due to allergic conjunctivitis and who do not have red eye(s) or more than 1.00 D of astigmatism. K-Lens contains an H1 histamine receptor antagonist for the prevention of itch associated with allergic conjunctivitis experienced by contact lens users (b) (4). The Sponsor states that prevention of itch has been demonstrated to last through 12 hours in clinical studies; however, the contact lens may be worn for longer than 12 hours for vision correction.

LABELING REVIEW:

The Sponsor submitted a Package Insert/Professional Fitting Guide, Patient Instructions, and carton and blister labeling for review. The submitted documents contain all of the appropriate warnings, precautions, contraindications and directions for use that are typical for normal contact lens use as detailed in the *1994 Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses*.

Parameter range comparison

The lens parameters are consistent with previously cleared daily disposable lenses marketed by this firm (K051900; K062614):

Diameter (DIA): 14.2 mm

Center Thickness: Minus Lens - varies with power (e.g. -4.00D: 0.084 mm)

Plus Lens - varies with power (e.g. +4.00D: 0.190 mm)

Base Curve (BC): 8.5 mm and 9.0 mm

Powers (D): -0.50D to -10.00D (in 0.25D increments)

-10.50D to -12.00D (in 0.50D increments)

+0.50D to +6.00D (in 0.25D increments)

CONCLUSIONS

Upon correction of the deficiency noted above, the labeling materials will be consistent with established FDA guidance for daily wear contact lenses for this NDA.

NAME

August 16, 2021

DATE COMPLETED

REFERENCES

21 CFR 800 GENERAL

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=800&showFR=1>

21 CFR 801 LABELING

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=801&showFR=1>

21 CFR 807 ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

Subpart E, § 807.87 - Information required in a premarket notification submission.

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=807.87>

1994 Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses

<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080928.htm>

Content of a 510(k) Guidance Document

<https://www.fda.gov/medical-devices/premarket-notification-510k/content-510k>

UDI Rule and Guidances, Training, Resources, and Dockets

<https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/udi-rule-and-guidances-training-resources-and-dockets>

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/s/

AHMED A AYODEJI
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