



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (jsh)

FOLDER: K100349 - 1071 pages

COMPANY: JOHNSON & JOHNSON VISION CARE, INC. (JOHNJOHNVISICARE)

PRODUCT: LENSES, SOFT CONTACT, DAILY WEAR (LPL)

SUMMARY: Product: VISTAKON (NARAFILCON B) CONTACT LENS VISIBILITY
TINTED WITH UV BLOCKER

DATE REQUESTED: Dec 20, 2012

DATE PRINTED: Dec 20, 2012

Note: Printed



MAY 21 2010

510(k) Summary

**Submitter
Information**

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

Contact Person: Catherine Dillon
Email: cdillon9@its.jnj.com
Telephone: 904-443-3180
FAX: 904-443-1424
Date Prepared: February 8, 2010

**Identification of
the Device**

Common Name: Soft Contact Lens
Device Name: VISTAKON® (narafilecon B) Contact Lens
Classification Name: Soft Hydrophilic Contact Lens, Daily Wear
Device Classification: Class II, 21 CFR 886.5925 (b) (1).

**Predicate
Device(s)****Material**

VISTAKON® (narafilecon A) Contact Lens – K073485
(FDA Group I; low water, nonionic polymer)

Indication, Wear Schedule

VISTAKON® (etafilecon A) Contact Lenses – K962804
(Daily wear, single use)

Continued on next page

510(k) Summary, Continued

Description of Device

- The VISTAKON® (narafilecon B) Contact Lens Visibility Tinted with UV Blocker is available as a spherical lens, multifocal lens, toric lens, and toric-multifocal lens.
- The lenses are made of a silicone hydrogel material containing an internal wetting agent.
- The VISTAKON® (narafilecon B) Contact Lens is tinted blue using Reactive Blue Dye #4 to make the lens more visible for handling.
- A benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics are less than 1% in the UVB range of 280 – 315nm and less than 10% in the UVA range of 316 – 380nm.
- The VISTAKON® (narafilecon B) Contact Lens is a hemispherical or hemitoric shell.
- The lens is supplied in a sterile state, packaged in a buffered saline solution with methyl ether cellulose.
- The composition of the lens is 52% narafilecon B and 48% water by weight when hydrated and stored in the buffered saline solution.

Continued on next page

510(k) Summary, Continued

Indications for Use

| Lens Design | Indication |
|--------------------|--|
| Spherical | The VISTAKON® (narafilecon B) Contact Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism. |
| Multifocal | The VISTAKON® (narafilecon B) Contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 4.00D of ADD power or less and 0.75D of astigmatism or less. |
| Toric | The VISTAKON® (narafilecon B) Contact Lens is indicated for daily wear single use only for the optical correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 4.00D of ADD power or less and 10.00D or less of astigmatism. |
| Multifocal Toric | The VISTAKON® (narafilecon B) Contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 4.00D of ADD power or less and 10.00D of astigmatism or less. |

- VISTAKON® (narafilecon B) Contact Lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.
- The Eye Care Professional should prescribe the lenses for daily wear single use only. The lenses are to be discarded upon removal; therefore, no cleaning or disinfection is required.

Continued on next page

510(k) Summary, Continued

Technological Characteristics

The technological characteristics of the VISTAKON[®] (narafilecon B) Contact Lenses are compared to the characteristics of the predicate device, VISTAKON[®] (narafilecon A) Contact Lens, in the following tables.

| Material Comparison | | |
|----------------------|--|--|
| | Predicate Device | Subject Device |
| Product Name | VISTAKON [®] (narafilecon A) Contact Lens | VISTAKON [®] (narafilecon B) Contact Lens |
| Material USAN Name | narafilecon A | narafilecon B |
| 510(k) Number | K073485 | TBD - This submission |
| FDA Category (Group) | Group I | Group I |
| Manufacturing Method | Molded | Molded |
| Sterilization | Moist Heat | Moist Heat |
| Packaging | Blister | Blister |
| Visibility Tint | Blue | Blue |

| Parameter Comparison | | | | |
|-------------------------|--|---------|--|---------|
| | Predicate Device VISTAKON [®] (narafilecon A) Contact Lens - K073485 | | Subject Device VISTAKON [®] (narafilecon B) Contact Lens | |
| | Measured | Labeled | Measured | Labeled |
| Water Content, % | 47 | 46 | 48 | 48 |
| Refractive Index @ 20°C | 1.40 | 1.41 | 1.41 | 1.41 |
| Dk, edge corrected | 96 | 100 | 52 | 55 |
| Base Curve, mm | 8.53 | 8.5 | 8.49 | 8.5 |
| Diameter, mm | 14.26 | 14.2 | 14.19 | 14.2 |
| Power, D | -0.92 | -1.00 | -0.98 | -1.00 |

*Polarographic Method, Dk units: $10^{-11}(\text{cm}^2/\text{sec})(\text{ml O}_2/\text{ml} \times \text{mmHg})$

Continued on next page

510(k) Summary, Continued

Non-clinical Testing

A series of *in-vitro* and *in-vivo* preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the contact lens. All tests were conducted in accordance with the GLP regulation (21 CFR Part 56) or according to valid scientific protocols.

The results of the non-clinical testing/evaluation demonstrate that:

- the lens material and/or extracts are non-toxic, non-irritating and non-sensitizing under the experimental conditions; and
 - the lens physical and material properties are consistent with currently marketed lenses.
-

Clinical Testing

A one-month clinical study was completed to evaluate the safety and efficacy of the VISTAKON® (narafileon B) Contact Lens for single use daily wear only.

The study evaluated 48 subjects with a 1:1 ratio between the test lens and the control lens (*1-DAY ACUVUE*® Brand Contact Lenses). The primary endpoints were slit lamp findings, symptoms, problems and complaints, visual acuity and average wear time. Additional parameters measured included adverse reactions, keratometry changes, reasons for discontinuation, and the number and reasons for unscheduled lens replacements.

The clinical evaluation demonstrated similar overall performance in the clinically relevant areas of vision and health as compared to concurrent controls when used under daily wear single use conditions.

Continued on next page

510(k) Summary, Continued

Conclusions Drawn from Studies

| | |
|-----------------------------|--|
| Validity of Scientific Data | A contract laboratory under Good Laboratory Practice Regulations conducted toxicology studies. Microbiology, chemistry, shelf-life stability, and leachability studies were conducted by VISTAKON® laboratories and followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7. |
| Substantial Equivalence | Information presented in this Premarket Notification establishes that the VISTAKON® (narafileon B) Contact Lens is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the requested indication. |
| Risk and Benefits | The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear single use basis. The benefits to the patient are the same as those for other soft (hydrophilic) contact lenses. |



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-0609
Silver Spring, MD 20993-0002

Johnson & Johnson Vision Care, Inc.
C/O Catherine C. Dillon
Regulatory Affairs
7500 Centurion Parkway, Suite 100
Jacksonville, FL 32256

MAY 21 2010

Re: K100349

Trade/Device Name: VISTAKON® (narafilecon B) Contact Lenses
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: May 4, 2010
Received: May 5, 2010

Dear Ms. Dillon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 – Ms. Catherine C. Dillon

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K100349

Device Name: VISTAKON® (narafilecon B) Contact Lens Visibility Tinted, with UV Blocker

Indications for Use:

The VISTAKON® (narafilecon B) Soft Contact Lens (spherical) is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The VISTAKON® (narafilecon B) Multifocal Soft Contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 4.00D of ADD power or less and 0.75D of astigmatism or less.

The VISTAKON® (narafilecon B) Toric Soft Contact Lens is indicated for daily wear single use only for the optical correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D or less of astigmatism.

The VISTAKON® (narafilecon B) Multifocal-Toric Soft Contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 4.00D of ADD power or less and 10.00D of astigmatism or less.

VISTAKON® (narafilecon B) Contact Lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

The Eye Care Professional should prescribe the lenses for daily wear single use only. The lenses are to be discarded upon removal; therefore, no cleaning or disinfection is required.

Prescription Use X And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen Wabunza
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K100349



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -W066-0609
Silver Spring, MD 20993-0002

Johnson & Johnson Vision Care, Inc.
C/O Catherine C. Dillon
Regulatory Affairs
7500 Centurion Parkway, Suite 100
Jacksonville, FL 32256

MAY 21 2010

Re: K100349

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Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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510(k) Number (if known): K100349

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Blocker

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Prescription Use X And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen Warburton
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K100349



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 05, 2010

JOHNSON & JOHNSON VISION CARE, INC.
7500 CENTURION PKWY. SUITE 100
JACKSONVILLE, FLORIDA 32256
UNITED STATES
ATTN: CATHERINE DILLON

510k Number: K100349

Product: VISTAKON (NARAFILCON B) CONTACT

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

April 27, 2010

JOHNSON & JOHNSON VISION CARE, INC.
7500 CENTURION PKWY. SUITE 100
JACKSONVILLE, FLORIDA 32256
UNITED STATES
ATTN: CATHERINE DILLON

510k Number: K100349

Product: VISTAKON (NARAFILCON B) CONTACT

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 12, 2010

JOHNSON & JOHNSON VISION CARE, INC.
7500 CENTURION PKWY. SUITE 100
JACKSONVILLE, FLORIDA 32256
UNITED STATES
ATTN: CATHERINE DILLON

510k Number: K100349

Received: 2/12/2010

Product: VISTAKON (NARAFILCON B) CONTAC

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, “Format for Traditional and Abbreviated 510(k)s”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

K100349

Johnson & Johnson
Vision Care, Inc. U.S. FOOD & DRUG ADMINISTRATION

February 8, 2010

FEB 12 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center -- WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Received

K110

RE: Premarket Notification - 510(k) Application for VISTAKON[®] (narafileon B) Contact Lens
Visibility Tinted, with UV Blocker

Dear Sir/Madam(s):

As required by section 510(k) of the Federal Food, Drug and Cosmetic Act, Johnson & Johnson Vision Care, Inc., is pleased to submit this premarket notification for the following Class II medical device:

| | |
|----------------------|---|
| Classification Name: | Daily Wear Soft Contact Lenses |
| Common/Usual Name: | Soft Contact Lenses |
| Device Name: | VISTAKON [®] (narafileon B) Contact Lens |

The lenses are made from a modified lens material, narafileon B. This submission contains information that demonstrates the substantial equivalence of the device to predicate control lenses in terms of material and performance characteristics. Testing which supports the substantial equivalence determination has been conducted as recommended in the May 1994 Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses and its flowchart.

Results from this comprehensive non-clinical and clinical evaluation demonstrate that the device is as safe and effective as the predicate devices and does not raise different questions regarding safety and effectiveness from the predicate device.

Per the instructions accessed at 'Electronic Copies for Pre-Market Submissions', an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission."

The existence of this 510(k) Premarket Notification and the data and other information that it contains are confidential, and the protection afforded to such confidential information by 18 USC 1905, 21 USC 331 (j), 5 USC 552, and other applicable laws is hereby claimed.

If there are any questions regarding this notification, please contact me at (904) 443-3180, email at cdillon9@its.jnj.com or Jacqueline Zimovan at (904) 443-1402, email at jzimovan@its.jnj.com

Sincerely,
Catherine C. Dillon

Catherine C. Dillon
Project Leader I
Regulatory Affairs

Johnson & Johnson
Vision Care, Inc.

510(k) Premarket Notification

VISTAKON[®] (narafilecon B) Contact Lens
For Single Use Daily Wear Only

Volume 1 of 3

February 8, 2010

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Section 1: Medical Device User Fee Coversheet

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

| | | | | |
|--|---|--|--|---|
| DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET | | PAYMENT IDENTIFICATION NUMBER: MD6047400-956733 Write the Payment Identification number on your check. | | |
| A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html | | | | |
| 1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) VISTAKON 7500 CENTURION PARKWAY SUITE 100 JACKSONVILLE FL 32256 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****8197 | 2. CONTACT NAME Catherine Dillon 2.1 E-MAIL ADDRESS cdillon9@its.jnj.com 2.2 TELEPHONE NUMBER (include Area code) 904-443-3180 2.3 FACSIMILE (FAX) NUMBER (Include Area code) | | | |
| 3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) Select an application type: <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice </td> <td style="width: 50%; vertical-align: top;"> 3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP) </td> </tr> </table> | | | <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice | 3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP) |
| <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice | 3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP) | | | |
| 4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: | | | | |
| 5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information) | | | | |
| 6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially </td> </tr> </table> | | | <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only | <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially |
| <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only | <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially | | | |
| 7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO | | | | |
| 8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION \$4,007.00 | | 18-Jan-2010 | | |

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)

JOHNSON AND JOHNSON VISION CARE, IN
C.
P.O. BOX 16500-6500
NEW BRUNSWICK, NJ 08906

00013-00346

00

Johnson & Johnson
SERVICES, INC.
As Paying Agent

FOOD AND DRUG ADMINISTRATION
PO BOX 956733 C/O US BANK LOCKBOX/
FDA ACCNT
SAINT LOUIS, MO 63195-6733

Check No.
Check Date
Check Amount
Vendor Number

(b)(4),(b)(6)

01/20/2010

(b)(4),(b)(6)

(b)(4),(b)(6)

| Invoice Date | Invoice Number | Description | Gross Amount | Discount Amount | Net Amount |
|--------------|----------------|--------------------------------|---------------|-----------------|---------------|
| 01/19/2010 | CR1986628 | FDA USER FEE - NARAFILCON B (C | (b)(4),(b)(6) | | (b)(4),(b)(6) |
| | | | | TOTAL | (b)(4),(b)(6) |

PAGE 1/1

(b)(4),(b)(6)

Section 2: FDA Forms

Contents

This section contains the following:

| Section | Topic | See Page |
|----------------|--|-----------------|
| 2.1 | Form FDA-3514, CDRH Premarket Review Submission Coversheet | 6 |
| 2.2 | Form FDA-3674, ClinicalTrials.gov Data Bank | 14 |
| 2.3 | Reviewers' Checklists | 16 |

2.1 CDRH Premarket Review Submission Coversheet

The Form FDA-3514, CDRH Premarket Review Submission Coversheet is provided in this section.

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

| | | |
|--|--|---|
| Date of Submission February 8, 2010 | User Fee Payment ID Number MD6047400-956733 | FDA Submission Document Number (if known) |
|--|--|---|

SECTION A TYPE OF SUBMISSION

| | | | | |
|--|--|---|--|--|
| <p>PMA</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement | <p>PMA & HDE Supplement</p> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other | <p>PDP</p> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP | <p>510(k)</p> <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party | <p>Meeting</p> <input type="checkbox"/> Pre-510(k) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify): |
| <p>IDE</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement | <p>Humanitarian Device Exemption (HDE)</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment | <p>Class II Exemption Petition</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information | <p>Evaluation of Automatic Class III Designation (De Novo)</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information | <p>Other Submission</p> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission): |

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

| | | | |
|---|-----------------------------|---|----------------|
| Company / Institution Name Johnson & Johnson Vision Care, Inc. | | Establishment Registration Number (if known) 1057985 | |
| Division Name (if applicable) | | Phone Number (including area code) 904-443-3180 | |
| Street Address 7500 Centurion Parkway | | FAX Number (including area code) 904-443-1424 | |
| City Jacksonville | State / Province Florida | ZIP/Postal Code 32256 | Country USA |
| Contact Name Catherine Dillon | | | |
| Contact Title Project Leader I, Regulatory Affairs | | Contact E-mail Address cdillon9@its.jnj.com | |

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

| | | | |
|-------------------------------|------------------|------------------------------------|---------|
| Company / Institution Name | | | |
| Division Name (if applicable) | | Phone Number (including area code) | |
| Street Address | | FAX Number (including area code) | |
| City | State / Province | ZIP Code | Country |
| Contact Name | | | |
| Contact Title | | Contact E-mail Address | |

| SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE | | |
|---|---|---|
| <input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site | <input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>) | <input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager |
| <input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (<i>specify below</i>) | <input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>) | <input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment |
| <input type="checkbox"/> Response to FDA correspondence: | | <input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address |
| <input type="checkbox"/> Other Reason (<i>specify</i>): | | |

| SECTION D2 REASON FOR APPLICATION - IDE | | |
|--|---|---|
| <input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access | <input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor | <input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing |
| <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final | | |
| <input type="checkbox"/> Other Reason (<i>specify</i>): | | |

| SECTION D3 REASON FOR SUBMISSION - 510(k) | | |
|--|---|---|
| <input type="checkbox"/> New Device | <input type="checkbox"/> Additional or Expanded Indications | <input type="checkbox"/> Change in Technology |
| <input checked="" type="checkbox"/> Other Reason (<i>specify</i>): Change in lens material. | | |

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

| | | | | | | | | | |
|--|-----|---|--|---|--|---|--|--|--|
| Product codes of devices to which substantial equivalence is claimed | | | | | | | | Summary of, or statement concerning, safety and effectiveness information | |
| 1 | LPL | 2 | | 3 | | 4 | | <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement | |
| 5 | | 6 | | 7 | | 8 | | | |

Information on devices to which substantial equivalence is claimed (if known)

| | 510(k) Number | | Trade or Proprietary or Model Name | | Manufacturer |
|---|---------------|---|--|---|-------------------------------------|
| 1 | K073485 | 1 | VISTAKON(R) (narafilecon A) Contact Lens | 1 | Johnson & Johnson Vision Care, Inc. |
| 2 | K962804 | 2 | VISTAKON(R) (etafilecon A) Contact Lens | 2 | Johnson & Johnson Vision Care, Inc. |
| 3 | | 3 | | 3 | |
| 4 | | 4 | | 4 | |
| 5 | | 5 | | 5 | |
| 6 | | 6 | | 6 | |

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Soft Hydrophilic Contact Lens, Daily Wear

| | Trade or Proprietary or Model Name for This Device | | Model Number |
|---|--|---|--------------|
| 1 | VISTAKON(R) (narafilecon B) Contact Lens | 1 | N/A |
| 2 | | 2 | |
| 3 | | 3 | |
| 4 | | 4 | |
| 5 | | 5 | |

FDA document numbers of all prior related submissions (regardless of outcome)

| | | | | | |
|---|---|---|----|----|----|
| 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 |

Data Included in Submission

- Laboratory Testing
 Animal Trials
 Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

| | | |
|--|---|---|
| Product Code LPL | C.F.R. Section (if applicable) 21 CFR 886.5925 | Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified |
| Classification Panel Ophthalmic Devices | | |

Indications (from labeling)

Provided on the following page.

Indications for Use

The VISTAKON[®] (narafilecon B) Soft Contact Lens (spherical) is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The VISTAKON[®] (narafilecon B) Multifocal Soft Contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less.

The VISTAKON[®] (narafilecon B) Toric Soft Contact Lens is indicated for daily wear single use only for the optical correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D or less of astigmatism.

The VISTAKON[®] (narafilecon B) Multifocal-Toric Soft Contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 10.00D of astigmatism or less.

VISTAKON[®] (narafilecon B) Contact Lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

The Eye Care Professional should prescribe the lenses for daily wear single use only. The lenses are to be discarded upon removal; therefore, no cleaning or disinfection is required.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

| | | | | |
|--|--|---|---|--|
| <input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | | Facility Establishment Identifier (FEI) Number 1057985 | <input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler | |
| Company / Institution Name Johnson & Johnson Vision Care, Inc. | | Establishment Registration Number 1057985 | | |
| Division Name (if applicable) | | Phone Number (including area code) 904-443-3180 | | |
| Street Address 7500 Centurion Parkway | | FAX Number (including area code) 904-443-1424 | | |
| City Jacksonville | | State / Province Florida | ZIP Code 32256 | Country USA |
| Contact Name Catherine Dillon | | Contact Title Project Leader I, Regulatory Affairs | | Contact E-mail Address cdillon9@its.jnj.com |

| | | | | |
|--|--|---|---|--|
| <input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | | Facility Establishment Identifier (FEI) Number 9617710 | <input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler | |
| Company / Institution Name Johnson & Johnson Vision Care (Ireland) | | Establishment Registration Number 9617710 | | |
| Division Name (if applicable) | | Phone Number (including area code) 904-443-3180 | | |
| Street Address The National Technology Park | | FAX Number (including area code) 904-443-1402 | | |
| City Limerick | | State / Province N/A | ZIP Code N/A | Country Ireland |
| Contact Name Catherine Dillon | | Contact Title Project Leader I, Regulatory Affairs | | Contact E-mail Address cdillon9@its.jnj.com |

| | | | | |
|---|--|--|--|------------------------|
| <input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | | Facility Establishment Identifier (FEI) Number | <input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler | |
| Company / Institution Name | | Establishment Registration Number | | |
| Division Name (if applicable) | | Phone Number (including area code) | | |
| Street Address | | FAX Number (including area code) | | |
| City | | State / Province | ZIP Code | Country |
| Contact Name | | Contact Title | | Contact E-mail Address |

SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

| | |
|---|--------|
| 1 | (b)(4) |
| 2 | |
| 3 | |
| 4 | |
| 5 | |
| 6 | |
| 7 | |

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

(b)(4)



2.2 ClinicalTrials.gov Data Bank Certification

Form FDA-3674, ClinicalTrials.gov Data Bank, is provided on the following pages.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

| | |
|--|---|
| 1. NAME OF SPONSOR/APPLICANT/SUBMITTER Johnson & Johnson Vision Care, Inc. | 2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES |
| 3. ADDRESS (Number, Street, State, and ZIP Code) 7500 Centurion Parkway Jacksonville, FL 32256 | 4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 904-443-1037 (Fax) 904-443-1424 |

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

VISTAKON (narafilecon B) Contact Lens

VISTAKON (ctafilcon A) Contact Lens

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

IND NDA ANDA BLA PMA HDE 510(k) PDP Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)
n/a

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
n/a

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)
NCT Number(s): NCT01031004

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

| | |
|---|--|
| 11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) | 12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) (b)(6) (Title) |
| 13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) 7500 Centurion Parkway, Suite 100 Jacksonville, FL 32256 | 14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 904-443-1037 (Fax) 904-443-1424 |
| | 15. DATE OF CERTIFICATION |

2.3 Reviewers' Checklists

**Reviewers'
Checklists**

The following two checklists are included in this section:

| Topic | See Page |
|--|-----------------|
| ODE Reviewer's Screening Checklist | 17 |
| Ophthalmic Devices Division Reviewer Checklist | 18 |

Continued on next page

2.3 Reviewers' Checklists, Continued

ODE Checklist The Office of Device Evaluation Reviewer's Screening Checklist is provided below.

| # | Item | Present | | Needed | Page |
|----|---|---------|----|---------|---------------------------|
| | | Yes | No | Yes/No? | |
| 1 | General Information | | | | |
| | • Reason for 510(k)/new or modified device | X | | Y | 72 |
| | • Trade and classification name | X | | Y | 72 |
| | • Establishment registration number | X | | Y | 72 |
| | • Device class | X | | Y | 72 |
| | • Meets special controls or performance standards | X | | Y | 72 |
| | • Identification of legally marketed device | X | | Y | 72 |
| 2 | Proposed Labeling, Labels, Advertisements | | | | |
| | • Description of new/modified device | X | | Y | 73 |
| | • Intended use statement | X | | Y | 34, 38, 67, 74, 87, 90 |
| | • Diagrams, engineering drawings, photographs (include diagrams) | X | | Y | 77, A |
| 3 | Comparisons of similarities/differences to named legally marketed device | | | | |
| | • Equivalent Device labeling, labels, advertising | X | | Y | 91 |
| | • Intended use of equivalent device | X | | Y | 87 |
| 4 | List of all patient contacting materials in new device | | | | |
| | • Include material specifications | | X | N | N/A |
| | • Comparison of materials to equivalent device | | X | N | N/A |
| 5 | Biocompatibility information/data for patient contacting materials | | | | |
| | • Identify color additive | | X | N | N/A |
| | • Certification – identical material/formulation | | X | N | N/A |
| 6 | Performance data | | | | |
| | • Bench data | X | | Y | 104 |
| | • Animal data | | X | N | 107 |
| | • Clinical data | X | | Y | 108, H |
| 7 | Sterilization information | X | | Y | 80, 93 |
| 8 | Software validation and verification | | X | N | N/A |
| 9 | 510(k) summary or statement | X | | Y | 35 |
| 10 | Truthful and Accurate Statement | X | | Y | 42 |
| 11 | If Class II, Class III Certification and Summary | | X | N | N/A |
| 12 | If kit, Kit Certification | | X | N | N/A |

Continued on next page

2.3 Reviewers' Checklists, Continued

Ophthalmic Checklist The Ophthalmic Devices Division of ODE for 510(k) review of contact lenses checklist is presented below.

| Attachment A Chemistry/Manufacturing | | | | | |
|---|------------|----------|------|-----|---------------|
| | Yes | No | Just | Inc | Page |
| 1. Claim of SE to lens material with an existing USAN? | | X | N/A | | N/A |
| a. Is the lens material generically equivalent to a currently marketed lens material? b. Same manufacturing process? i. Analysis of justification, if necessary, for any difference in physicochemical properties c. Different manufacturing process? i. Clinical performance data provided? ii. Side-by-side comparison provided? iii. Analysis/justification for any differences noted in (ii)? | | | | | |
| 2. Claim of SE to lens material with the same USAN name with a different suffix? | X | | | | 82 |
| If applicant is proposing a modification to the lens material, has the following been demonstrated/provided: a. Modified lens has an approved parent USAN b. Modified lens falls into one of the lens groups c. Side-by-side comparison of physicochemical properties of proposed lens compared with predicate device d. If lens is an RGP lens, modulus, toughness, and flexural strength are in the ranges of approved lenses in that lens group e. Appropriate clinical performance data which demonstrate SE | Y | | | | 72, F |
| | Y | | | | 72 |
| | Y | | | | 106 |
| | N/A | | | | N/A |
| | Y | | | | 108, H |
| 3. Claim of SE to a lens material with a new USAN name? | | X | N/A | | N/A |
| Has the following been demonstrated/provided? a. Lens falls into one of the lens groups b. Approved USAN name c. Lens physicochemical properties d. Appropriate clinical performance data which demonstrate SE | | | | | |

Continued on next page

2.3 Reviewers' Checklists, Continued

| Chemistry/Manufacturing, (continued) | | | | | |
|---|----------|----------|------------|-----|------------|
| | Yes | No | Just | Inc | Page |
| 4. Has the following manufacturing/chemistry data been provided? (pages 18-21, Guidance Document) | X | | | | |
| a. Chemical composition of lens and purity of each monomer component | X | | | | 76 |
| b. Manufacturing information | X | | | | 80 |
| c. Shelf-life | X | | | | 94 |
| d. Compatibility testing | N | | N/A | | N/A |
| e. Leachability | Y | | | | 105 |
| f. Finished lens parameters | Y | | | | 77 |
| g. Preservative uptake/release | N | | N/A | | N/A |
| h. Side-by-side comparison of physicochemical/optical properties of proposed lens compared with predicate device | Y | | | | 106 |
| 5. Has it been demonstrated that the lens blank is safe and effective for their intended use? | | X | N/A | | N/A |
| a. Has lens blank manufacturer received 510(k) clearance for the lens blank? | | | | | |
| b. Does the 510(k) contain preclinical data or an authorized reference to an applicable Device Master File? | | | | | |
| 6. Claim for SE based on a modification to the contact lens material? (See p. 22 of Guidance Document for examples of modifications) | | X | N/A | | N/A |
| a. Do any physical/chemical/optical and toxicological data vary from predicate device (side-by-side)? | | | | | |
| b. Justification for any variances in 6a? | | | | | |

Continued on next page

2.3 Reviewers' Checklists, Continued

| Attachment B Toxicology | | | | | |
|--|-----|----|------|-----|-------|
| | Yes | No | Just | Inc | Page |
| 1. Have preclinical studies been conducted? | X | | | | 99, E |
| a. Systemic Injection Test (**) | | X | Y | | 99 |
| b. Eye Irritation Test (**) | X | | | | 99, E |
| c. Cytotoxicity Test (**) | X | | | | 99, E |
| 2. Is Material Safety Data Sheet (MSDS) provided? | X | | | | 98, D |
| a. Will MSDS be used in lieu of additional toxicity testing? | | X | N/A | | N/A |
| 3. Has applicant provided documentation demonstrating either: | | X | N/A | | N/A |
| a. Recommended lens care regimen has been approved for use with the specific lens material group (filcon/focon or hydrophilic/hydrophobic), OR | | | | | |
| b. Plastic lens carries no charge or has the same electric charge as the preservative system used in the recommended lens care regimen? | | | | | |
| If yes, no additional toxicity* testing recommended. | | | | | |
| If no, proceed to Question 4. | | | | | |
| 4. If the answer to (3) is no, or a plastic material is manufactured using a new monomer, OR a new UV-absorber is incorporated into the material, has the applicant provided test data for: | X | | | | |
| a. Preservative Uptake and Release | | X | N/A | | N/A |
| b. Guinea Pig Maximization Test | | X | Y | | 99 |
| c. Three-week Ocular Irritation Test | | X | Y | | 99 |
| 5. Has applicant provided scientific justification for not conducting any of the above listed testing? | X | | | | 99 |
| 6. If the contact lens is a hydrophilic (soft) lens, has the applicant conducted the following toxicology tests on the plastic container in which the contact lens is stored to determine potential leaching of the container constituents: | X | | | | 101 |
| a. Data provided for the Systemic Injection Test (USP) | X | | | | 101 |
| b. Data provided for the Eye Irritation Test (USP) | X | | | | 101 |
| c. Data provided for the Cytotoxicity Test (USP) | X | | | | 101 |

* Preservative Uptake and Release, Guinea Pig Maximization Test, Three-week Ocular Irritation Study

** United States Pharmacopoeia XXI/National Formulary XVI (or current update)

Continued on next page

2.3 Reviewers' Checklists, Continued

| Attachment C Microbiology | | | | | |
|---|----------|----------|----------|-----|-----------|
| | Yes | No | Just | Inc | Page |
| 1. Validation of Sterilization System and Cycle for Soft (hydrophilic) Contact Lenses | X | | | | 93 |
| The following information should be provided | | | | | |
| a. Sterilization method used (Steam, Ethylene Oxide (EtO), Gamma or Electron Beam Radiation). | | | | | |
| i. Has applicant stated which method was used to develop the sterilization cycle? | | | | | |
| A. Overkill Method | X | | | | 93 |
| B. Bioburden Method | | | | | |
| b. If no acceptable reference (see next page) was provided, did application include a description of the validation method? | | | | | |
| A. Installation Qualification | | | | | |
| B. Operational Qualification | | | | | |
| C. Performance Qualification (including a Sterility Assurance Level (SAL) of at least 10 ⁻⁶) | | | | | |
| c. Description of the device packaging to maintain sterility. | X | | | | 93 |
| d. If EtO sterilization, maximum residue levels of EtO, ethylene chlorhydrin, and ethylene glycol which remain on the device. | | | | | |
| e. If radiation sterilization, the radiation dose | | | | | |
| 2. Efficacy of the Sterilization System | X | | | | 93 |
| a. A description of the Q/A procedures and methods used for sterility testing to provide routine sterility assurance of each batch of lenses should be provided. Product sterility testing should follow USP methods. | | | | | |
| After the sterilization cycle has been validated with the use of biological indicators, the routine release of product through use of validated bioindicators alone is acceptable (see p. 40, Guidance Document) | | | | | |
| Acceptable references for sterilization methods are: | | | | | |
| ANSI/AAMI/ISO 11134: "Industrial Moist Heat Sterilization" | | X | X | | 93 |
| PDA Technical Monograph No. 1: "Validation of Steam Sterilization" | | | | | |

Continued on next page

2.3 Reviewers' Checklists, Continued

| Microbiology, (continued) | | | | | |
|---|-----|----|------|-----|-------|
| | Yes | No | Just | Inc | Page |
| 3. Are there any changes to the sterilization process? | | X | N/A | | N/A |
| a. change in method b. change to parametric release c. change in device packaging | | | | | |
| 4. Has shelf-life data been provided in accordance with guidance recommendations (p. 41)? | X | | | | 94 |
| 5. Does data demonstrate that the contact lenses remain sterile for the proposed shelf-life? | X | | | | 94 |
| HYDROPHOBIC CONTACT LENSES | | | | | |
| <2% Water Content: | | | | | |
| For hydrophobic contact lenses with a water content of less than 2%, the manufacturer is required to provide the following (see pages 43-44, Guidance Document): | | | | | |
| 1. Data to indicate an average bioburden level of <100cfu/lens | | X | N/A | | |
| 2. Quality Assurance measurements to ensure consistently low bioburden levels | | X | N/A | | |
| 3. Routine bioburden monitoring program Labeling for RGP lenses is addressed in the Labeling section of the Guidance Document | | X | N/A | | |
| >2% but <10% Water Content: | | | | | |
| The following requirements, in addition to the above requirements for <2% water lenses, are for contact lenses with a water content of more than 2% but less than 10%: | | | | | |
| 1. Studies demonstrating that the lenses do not support the growth microorganisms as routinely manufactured, packaged and stored? (min. 10 lenses/lot randomly selected from a min. of 2 lots manufactured at least 1 month apart). | | X | N/A | | N/A |
| 2. Shelf-life studies using the same lots and sample sizes demonstrating that the bioburden levels remain constant or decrease upon storage at ambient conditions | | X | N/A | | N/A |
| BOTH HYDROPHILIC AND HYDROPHOBIC SOFT CONTACT LENSES | | | | | |
| 1. Has applicant provided adequate labeling of manufacturer recommendations for lens cleaning and disinfection by the consumer? | X | | | | 89, G |
| 2. If the contact lens material is of a new lens group that has not been approved for use with the lens care regimen, has the Multi-item Microbial Challenge Test been conducted? | | X | N/A | | N/A |

Continued on next page

2.3 Reviewers' Checklists, Continued

| Attachment D Clinical | | | | | |
|---|-----|----|------|-----|--------|
| | Yes | No | Just | Inc | Page |
| 1. Claim of SE to lens material with the same USAN name? | | X | N/A | | N/A |
| a. Same manufacturing process (clinical performance data not required)? i. Do physical/chemical/optical and preclinical data support SE claim? ii. Is clinical data required? b. Different manufacturing process? i. Do any physical/chemical/optical and preclinical data fall outside the range established by the test methodology? ii. Justification provided for any physical/chemical/optical and/or preclinical data discrepancy identified in b(i)? iii. If clinical data is required, does the study design/protocol conform to recommended protocol in the Guidance Document (pgs. 48, 53, 54)? (30 subjects for 30 days) iv. Have appropriate explanations been provided where necessary? | | | | | |
| 2. Claim of SE to lens material with a modified USAN | X | | | | 72 |
| a. Is clinical performance data provided? (30 subjects for 30 days) | X | | | | 108, H |
| b. Does the study design/protocol conform to recommended protocol in the Guidance Document (pgs. 48, 53, 54)? | X | | | | 108, H |
| 3. Claim of SE to a lens material with a different USAN name? | | X | N/A | | N/A |
| a. Is clinical performance data provided? (50 subjects for 3 months) b. Does the study design/protocol conform to recommended protocol in the Guidance Document (pgs. 48, 53, 54)? | | | | | |
| 4. Is there a Special Use Indication or additional labeling claim of Enhanced Indication? | | X | N/A | | N/A |
| a. Is predicate device legally marketed in the U.S. with the same intended use? b. Is study design provided demonstrating SE to this predicate device? | | | | | |

* Utilize Draft Guidance.

Continued on next page

2.3 Reviewers' Checklists, Continued

| Clinical, (continued) | | | | | |
|--|-----|----|------|-----|------|
| | Yes | No | Just | Inc | Page |
| 5. Claim for SE based on lens modifications | | X | NA | | NA |
| a. Is there a modification to the contact lens material? <ol style="list-style-type: none"> i. is physical/chemical/optical and pre-clinical data sufficient to support a SE claim? ii. if no, are clinical data provided following guidance recommendations? (30 subjects for 30 days) b. Is applicant requesting an alternate design configuration? (complete only if a bifocal) <ol style="list-style-type: none"> i. does the intended use include correction of presbyopic patients by a bifocal (bifocal) lens? (p. 51, Guidance Document) ii. if this is an original 510(k), has applicant provided a statement that preclinical and clinical performance data are equally applicable to the new alternate lens design? iii. if this is a separate 510(k), has applicant provided reference to the SE 510(k) for the lens material used to make the alternate lens design? iv. has applicant provided <ul style="list-style-type: none"> • engineering drawing and narrative description of the new lens • optical explanation and theory of how the lens works • justification of the design in terms of the requested labeling indications • complete description of manufacturing techniques. A minimum of 10 lenses should be manufactured and verified that the finished lenses meet specific tolerances • proper labeling (p. 52 Guidance Doc.) | | | | | |

For those applications that contain clinical data, the following study parameters should have been addressed. The next page lists these parameters to aid in your review of the clinical study(ies). Missing or inadequate data will need to be discussed with the applicant.

Continued on next page

2.3 Reviewers' Checklists, Continued

| Clinical, (continued) | | | | | |
|---|-----|----|------|-----|-------------------|
| | Yes | No | Just | Inc | Page |
| Clinical Findings to Determine Safety and Effectiveness | X | | | | 108 |
| 1. Demographics | | X | N/A | | N/A |
| a. Does the total number of enrolled patients equal the number of completed patients in the study? | | X | | | 110 |
| b. Are discontinued patients accounted for? | X | | | | 110 |
| c. Is there adequate representation of both female and male subjects? | X | | | | H-24 |
| d. Are exclusion criteria provided? | X | | | | H-22 |
| e. Does the clinical study follow the recommended protocol in the guidance document? | X | | | | 110 |
| 2. Safety | X | | | | H-35 |
| a. Are any symptoms, problems and complaints addressed? | X | | | | H-37 |
| b. Are any adverse reactions noted? | X | | | | H-41 |
| c. If any symptom/reaction is identified for 2a or 2b, is it expected for the proposed use of the device? | X | | | | H-37, H-41 |
| d. Slit lamp findings provided? | X | | | | H-35 |
| e. Study period and lens wear time indicated? | X | | | | H-27, H-40 |
| 3. Effectiveness | X | | | | H-39 |
| a. Visual acuity data provided? | X | | | | H-39 |
| b. Number of lens replacement(s) noted? | X | | | | H-45 |

Continued on next page

2.3 Reviewers' Checklists, Continued

| Attachment Eye Care Practitioner Labeling | | | | | |
|---|-----|----|------|-----|-----------------------------------|
| | Yes | No | Just | Inc | Page |
| 1. Have the following pieces of labeling been provided? | X | | | | 89, G |
| a. Package Insert? | X | | | | G-5 |
| b. Professional Fitting and Information Guide? | X | | | | G-5 |
| c. Patient Instructions? | X | | | | G-30 |
| d. Container/Vial Label? | X | | | | G-2 |
| e. Appropriate labeling for UV-Light absorbing contact lens (see Labeling, Appendix E, pgs. 138 and 139 of the May 12, 1994 Guidance Document) in the Description section, if applicable? | X | | | | G-8 |
| 2. Do the Indications for use stated in the labeling reflect the same indications for use as they appear in the text of the application? | X | | | | 34, 38, 67, 74, 87, 90, G-9, G-32 |
| 3. If applicable, does the labeling include a description of the color additive? Does the Precautions section of the Package Insert state "Patients may experience a reduction in visibility while wearing this lens in conditions of low illumination" if the light transmission of a tinted lens is 70% or less in the visible range of 380 – 780nm? (see Labeling, Appendix E, p. 105 of the May 12, 1994 Guidance Document) | | X | N/A | | N/A |
| 4. If the contact lens is indicated for presbyopia, has the labeling section for "monovision" wear been modified to reflect the presbyopic lens? (see Labeling, Appendix E, p. 123 of the May 12, 1994 Guidance Document) | X | | | | G-41 |
| 5. If the contact lens is a Rigid Gas Permeable contact lens (hydrophobic), does the labeling state in the Caution section and on the package labeling "Caution, Non-Sterile. Clean and condition lenses prior to use."? | | X | N/A | | N/A |
| 6. If there has been a modification of lens power or dimensional parameter to the lens, does Precautions statement in the Professional Fitting and Information Guide include the following, "Due to the small number of patients..." (see Clinical section, p. 50, item 2b of May 12, 1994 Guidance Document)? | | X | N/A | | N/A |
| 7. Is a lens care regimen approved for use with these contact lenses? | X | | | | G-41 |
| 8. Does the labeling follow the format both in content as well as presentation as provided in the guidance document? | X | | | | G |

Continued on next page

2.3 Reviewers' Checklists, Continued

| Adding Contact Lens Finishing Laboratories for RGP Contact Lenses (For Rigid Gas Permeable (Hydrophobic) Contact Lenses) | | | | | |
|--|-----|----|------|-----|------|
| | Yes | No | Just | Inc | Page |
| 1. A 510(k) application for a protocol for the addition of contact lens finishing laboratories for is required in two situations: | | X | N/A | | N/A |
| <p>a. If the applicant has a previously approved PMA, PMA supplement, or an SE 510(k) for daily wear RGP lenses but <u>does not</u> have CDRH clearance for adding finishing laboratories, OR,</p> <p>b. If the applicant <u>does not</u> have a previously approved PMA, PMA supplement, or an SE 510(k) and intends to use independent contact lens finishing laboratories for the manufacture and marketing of the finished device(s).</p> | | | | | |
| 2. If the 510(k) meets the criteria for 1(a), did the applicant provide the following data in the application: | | X | N/A | | N/A |
| <p>a. a sworn certification completed, signed, and dated by a responsible company official stating that the manufacturer will comply with all requirements set forth in this procedure and will assume responsibility for ensuring the quality and traceability of the finished RGP lens to the lot or batch of material as identified by the manufacturer, and,</p> <p>b. the documentation and information as outlined in section II, A-F, pgs. 142-144 of the May 12, 1994 Guidance Document or authorization to reference an approved protocol for the addition of alternate finishing laboratories for daily wear RGP contact lenses.</p> | | | | | |

Continued on next page

2.3 Reviewers' Checklists, Continued

| Adding Contact Lens Finishing Laboratories for RGP Contact Lenses (For Rigid Gas Permeable (Hydrophobic) Contact Lenses) | | | | | |
|--|------------|-----------|-------------|------------|-------------|
| | Yes | No | Just | Inc | Page |
| 3. If the 510(k) meets the criteria for 1(b), did the applicant provide the following data in a COMPLETE 510(k) application as specified in the PREMARKET NOTIFICATION (510(k) GUIDANCE DOCUMENT FOR DAILY WEAR CONTACT LENSES: | | X | N/A | | N/A |
| <p>a. a sworn certification completed, signed, and dated by a responsible company official stating that the manufacturer will comply with all requirements set forth in this procedure and will assume responsibility for ensuring the quality and traceability of the finished RGP lens to the lot or batch of material as identified by the manufacturer and,</p> <p>b. the documentation and information as outlined in section II, A-F, pgs. 142-144 of the May 12, 1994 Guidance Document or authorization to reference an approved protocol for the addition of alternate finishing laboratories for daily wear RGP contact lenses.</p> <p>Applicants given clearance or with prior approval for a protocol for adding contact lens finishing laboratories should retain the documentation listed on pages 142-1544 on site in the device master record by the manufacturer and made available upon request.</p> | | | | | |

Continued on next page

2.3 Reviewers' Checklists, Continued

| Color Additives and Contact Lenses | | | | | |
|--|-----|----|------|-----|------|
| | Yes | No | Just | Inc | Page |
| 1. A 410(k) application for a protocol for the addition of LISTED color additives is required in two situations: | | X | N/A | | N/A |
| <p>a. If the applicant has a previously approved PMA, PMA supplement, or an SE 510(k) for daily wear RGP lenses but <u>does not</u> have CDRH clearance for the incorporation of a listed color additive in the contact lens material, OR</p> <p>b. If the applicant does not have a previously approved PMA, PMA supplement, or an SE 510(k) for a daily wear RGP contact lens and intends to incorporate a listed color additive in the contact lens material.</p> | | | | | |
| 2. If the 510(k) meets the criteria for 1(a) or 1(b), did the applicant provide: | | X | N/A | | N/A |
| <p>a. a COMPLETE 510(k) application as specified in the PREMARKET NOTIFICATION (510(k)) GUIDANCE DOCUMENT FOR DAILY WEAR CONTACT LENSES, and,</p> <p>b. a sworn certification completed, signed, and dated by a responsible company official stating that the manufacturer will comply with all testing and document requirements set forth in this procedure and will assume responsibility for ensuring the quality of the finished lenses.</p> | | | | | |
| If a daily wear contact lens manufacturer <u>deviates</u> from any part of the procedure for incorporating listed color additives in contact lenses as specified in the Guidance Document on pages 151-153, a new 510(k) should be submitted and a "SE" determination received from CDRH before implementing the change. | | X | N/A | | N/A |
| Applicants given clearance or with prior approval for the incorporation of listed color additives in contact lens materials should retain the documentation as listed on pages 152 and 153 of the Guidance Document on-site in the device master record by the manufacturer and made available upon request. | | X | N/A | | N/A |

Continued on next page

2.3 Reviewers' Checklists, Continued

| Changes in Packaging Materials | | | | | |
|---|-----|----|------|-----|------|
| | Yes | No | Just | Inc | Page |
| Changes in Packaging Materials | | X | N/A | | N/A |
| 1. Does applicant have prior approval or clearance to manufacture a daily wear contact lens? If no: | | | | | |
| <p>a. Has the applicant submitted a COMPLETE 510(k) as specified in the PREMARKET NOTIFICATION 510(k) GUIDANCE DOCUMENT FOR DAILY WEAR CONTACT LENSES, and,</p> <p>b. Has the applicant included a sworn certification completed, signed, and dated by a responsible company official stating that the manufacturer will comply with all testing and document requirements set forth in this procedure and will assume responsibility for ensuring the compatibility of the contact lens material with the storage solution, container, closure or other plastic components, and will assure that the changes in packaging will not compromise the sterility or stability of the finished contact lens, and</p> | | | | | |
| If yes (and also after clearance has been received for a daily wear contact lens): | | | | | |
| <p>a. The applicant must retain the sworn certification as described above, and all documentation and information as outlined in the Procedure for Implementing Changes in Packaging Materials, item II, on page 155 which should be available upon request.</p> | | | | | |
| <p>If a daily wear contact lens manufacturer <u>deviates</u> from any part of the procedure for implementing changes in packaging materials as specified in the Guidance Document on pages 155 and 156, a new 510(k) should be submitted and a "SE" determination received from CDRH before implementing the change.</p> | | | | | |

Section 3: Cover Letter

Johnson & Johnson
Vision Care, Inc.

February 8, 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Premarket Notification - 510(k) Application for VISTAKON[®] (narafilecon B) Contact Lens
Visibility Tinted, with UV Blocker

Dear Sir/Madam(s):

As required by section 510(k) of the Federal Food, Drug and Cosmetic Act, Johnson & Johnson Vision Care, Inc., is pleased to submit this premarket notification for the following Class II medical device:

| | |
|----------------------|--|
| Classification Name: | Daily Wear Soft Contact Lenses |
| Common/Usual Name: | Soft Contact Lenses |
| Device Name: | VISTAKON [®] (narafilecon B) Contact Lens |

The lenses are made from a modified lens material, narafilecon B. This submission contains information that demonstrates the substantial equivalence of the device to predicate control lenses in terms of material and performance characteristics. Testing which supports the substantial equivalence determination has been conducted as recommended in the May 1994 Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses and its flowchart.

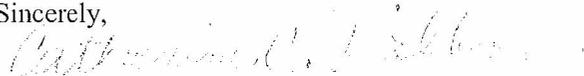
Results from this comprehensive non-clinical and clinical evaluation demonstrate that the device is as safe and effective as the predicate devices and does not raise different questions regarding safety and effectiveness from the predicate device.

Per the instructions accessed at 'Electronic Copies for Pre-Market Submissions', an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission."

The existence of this 510(k) Premarket Notification and the data and other information that it contains are confidential, and the protection afforded to such confidential information by 18 USC 1905, 21 USC 331 (j), 5 USC 552, and other applicable laws is hereby claimed.

If there are any questions regarding this notification, please contact me at (904) 443-3180, email at cdillon9@its.jnj.com or Jacqueline Zimovan at (904) 443-1402, email at jzimovan@its.jnj.com

Sincerely,



Catherine C. Dillon
Project Leader I
Regulatory Affairs

Section 4: Indications for Use Statement

Indications for Use Statement

510(k) Number (if known):

Device Name: VISTAKON[®] (narafileon B) Contact Lens Visibility Tinted, with UV
Blocker

Indications for Use:

The VISTAKON[®] (narafileon B) Soft Contact Lens (spherical) is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The VISTAKON[®] (narafileon B) Multifocal Soft Contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less.

The VISTAKON[®] (narafileon B) Toric Soft Contact Lens is indicated for daily wear single use only for the optical correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D or less of astigmatism.

The VISTAKON[®] (narafileon B) Multifocal-Toric Soft Contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 10.00D of astigmatism or less.

VISTAKON[®] (narafileon B) Contact Lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

The Eye Care Professional should prescribe the lenses for daily wear single use only. The lenses are to be discarded upon removal; therefore, no cleaning or disinfection is required.

Prescription Use X _____ And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5: 510(k) Summary

510(k) Summary

Submitter Information

Company: Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Suite 100
Jacksonville, FL 32256
Contact Person: Catherine Dillon
Email: cdillon9@its.jnj.com
Telephone: 904-443-3180
FAX: 904-443-1424
Date Prepared: February 8, 2010

Identification of the Device

Common Name: Soft Contact Lens
Device Name: VISTAKON[®] (narafileon B) Contact Lens
Classification Name: Soft Hydrophilic Contact Lens, Daily Wear
Device Classification: Class II, 21 CFR 886.5925 (b) (1).

Predicate Device(s)

Material

VISTAKON[®] (narafileon A) Contact Lens – K073485
(FDA Group I; low water, nonionic polymer)

Indication, Wear Schedule

VISTAKON[®] (etafileon A) Contact Lenses – K962804
(Daily wear, single use)

| |
|---|
| Note: The VISTAKON [®] (narafileon A) Contact Lens has not been marketed in the United States. |
|---|

Continued on next page

510(k) Summary, Continued

Description of Device

- The VISTAKON[®] (narafileon B) Contact Lens Visibility Tinted with UV Blocker is available as a spherical lens, multifocal lens, toric lens, and toric-multifocal lens.
- The lenses are made of a silicone hydrogel material containing an internal wetting agent.
- The VISTAKON[®] (narafileon B) Contact Lens is tinted blue using Reactive Blue Dye #4 to make the lens more visible for handling.
- A benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics are less than 1% in the UVB range of 280 – 315nm and less than 10% in the UVA range of 316 – 380nm.
- The VISTAKON[®] (narafileon B) Contact Lens is a hemispherical or hemitoric shell.
- The lens is supplied in a sterile state, packaged in a buffered saline solution with methyl ether cellulose.
- The composition of the lens is 52% narafileon B and 48% water by weight when hydrated and stored in the buffered saline solution.

Continued on next page

510(k) Summary, Continued

Indications for Use

| Lens Design | Indication |
|--------------------|---|
| Spherical | The VISTAKON [®] (narafilecon B) Contact Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism. |
| Multifocal | The VISTAKON [®] (narafilecon B) Contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less. |
| Toric | The VISTAKON [®] (narafilecon B) Contact Lens is indicated for daily wear single use only for the optical correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D or less of astigmatism. |
| Multifocal Toric | The VISTAKON [®] (narafilecon B) Contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 10.00D of astigmatism or less. |

- VISTAKON[®] (narafilecon B) Contact Lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.
- The Eye Care Professional should prescribe the lenses for daily wear single use only. The lenses are to be discarded upon removal; therefore, no cleaning or disinfection is required.

Continued on next page

510(k) Summary, Continued

Technological Characteristics The technological characteristics of the VISTAKON[®] (narafilecon B) Contact Lenses are compared to the characteristics of the predicate device, VISTAKON[®] (narafilecon A) Contact Lens, in the following tables.

| Material Comparison | | |
|----------------------------|--|--|
| | Predicate Device | Subject Device |
| Product Name | VISTAKON [®] (narafilecon A) Contact Lens | VISTAKON [®] (narafilecon B) Contact Lens |
| Material USAN Name | narafilecon A | narafilecon B |
| 510(k) Number | K073485 | TBD - This submission |
| FDA Category (Group) | Group I | Group I |
| Manufacturing Method | Molded | Molded |
| Sterilization | Moist Heat | Moist Heat |
| Packaging | Blister | Blister |
| Visibility Tint | Blue | Blue |

| Parameter Comparison | | | | |
|-----------------------------|---|----------------|---|----------------|
| | Predicate Device VISTAKON [®] (narafilecon A) Contact Lens – K073485 | | Subject Device VISTAKON [®] (narafilecon B) Contact Lens | |
| | Measured | Labeled | Measured | Labeled |
| Water Content, % | 47 | 46 | 48 | 48 |
| Refractive Index @ 20°C | 1.40 | 1.41 | 1.41 | 1.41 |
| Dk, edge corrected | 96 | 100 | 52 | 55 |
| Base Curve, mm | 8.53 | 8.5 | 8.49 | 8.5 |
| Diameter, mm | 14.26 | 14.2 | 14.19 | 14.2 |
| Power, D | -0.92 | -1.00 | -0.98 | -1.00 |

*Polarographic Method, Dk units: $10^{-11}(\text{cm}^2/\text{sec})(\text{ml O}_2/\text{ml x mmHg})$

Continued on next page

510(k) Summary, Continued

Non-clinical Testing

A series of *in-vitro* and *in-vivo* preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the contact lens. All tests were conducted in accordance with the GLP regulation (21 CFR Part 56) or according to valid scientific protocols.

The results of the non-clinical testing/evaluation demonstrate that:

- the lens material and/or extracts are non-toxic, non-irritating and non-sensitizing under the experimental conditions; and
 - the lens physical and material properties are consistent with currently marketed lenses.
-

Clinical Testing

A one-month clinical study was completed to evaluate the safety and efficacy of the VISTAKON[®] (narafileon B) Contact Lens for single use daily wear only.

The study evaluated 48 subjects with a 1:1 ratio between the test lens and the control lens (*1-DAY ACUVUE[®]* Brand Contact Lenses). The primary endpoints were slit lamp findings, symptoms, problems and complaints, visual acuity and average wear time. Additional parameters measured included adverse reactions, keratometry changes, reasons for discontinuation, and the number and reasons for unscheduled lens replacements.

The clinical evaluation demonstrated similar overall performance in the clinically relevant areas of vision and health as compared to concurrent controls when used under daily wear single use conditions.

Continued on next page

510(k) Summary, Continued

Conclusions Drawn from Studies

| | |
|-----------------------------|--|
| Validity of Scientific Data | A contract laboratory under Good Laboratory Practice Regulations conducted toxicology studies. Microbiology, chemistry, shelf-life stability, and leachability studies were conducted by VISTAKON® laboratories and followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7. |
| Substantial Equivalence | Information presented in this Premarket Notification establishes that the VISTAKON® (narafileon B) Contact Lens is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the requested indication. |
| Risk and Benefits | The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear single use basis. The benefits to the patient are the same as those for other soft (hydrophilic) contact lenses. |

Section 6: Truthful and Accuracy Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Project Leader I, Regulatory Affairs of Johnson & Johnson Vision Care, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Catherine C. Dillon
Project Leader
Regulatory Affairs

Date

*(Premarket Notification [510(k)] Number)

Section 7: Class III Summary and Certification

This section is not applicable.

Section 8: Financial Certification or Disclosure Statement

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

- (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

| Clinical Investigators | (b)(6) | | |
|------------------------|--------|--|--|
| | | | |
| | | | |
| | | | |

- (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

- (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

| NAME | TITLE |
|--|-------------------|
| (b)(6) | |
| FIRM/ORGANIZATION JOHNSON & JOHNSON VISION CARE, INC. | |
| SIGNATURE | DATE (mm/dd/yyyy) |
| (b)(6) | 01/27/2010 |

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

Section 9: Declarations of Conformity and Summary Reports

Form FDA-3654 Standards Data Report for 510(k)s is provided for the following referenced standards in this section:

- (b)(4)
 -
 -
 -
 -
 -
 -
 -
 -
-

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

(b)(4)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # (b)(4)

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

AAMI / ANSI / ISO 17665-1: Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, 2006

CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|---|
| N/A | N/A | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED *
See Attachment I for documentation of extent of conformance.

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|---|
| | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|---|
| | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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Department of Health and Human Services
Food and Drug Administration
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

(b)(4)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # (b)(4)

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Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

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⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

(b)(4)

CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|---|
| N/A | N/A | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

Please see Attachment I for documentation of extent of conformance

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|---|
| | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|---|
| | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

(b)(4)

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Yes No

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FDA Recognition number ³ (b)(4) _____

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Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html
³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>
⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>
⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

(b)(4)

CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|---|
| N/A | N/A | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

Please see Attachment I for documentation of extent of conformance

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|---|
| | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|---|
| | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

† Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

(b)(4)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ (b)(4) _____

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
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Title of guidance: _____

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

(b)(4)

CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|--|
| N/A | N/A | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED *
See Attachment I for documentation of extent of conformance

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|---|
| | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|---|
| | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

(b)(4)

Please answer the following questions

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FDA Recognition number³ # (b)(4)

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