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

K100349

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

Indication, Wear Schedule
VISTAKON® (etafilcon A) Contact Lenses – K962804
(Daily wear, single use)

Continued on next page

510(k) Summary, Continued

Description of Device

- The VISTAKON® (narafilcon 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® (narafilcon 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® (narafilcon 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% narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon B) Contact Lenses are compared to the characteristics of the predicate device, VISTAKON® (narafilcon A) Contact Lens, in the following tables.

Material Comparison		
	Predicate Device	**Subject Device**
Product Name	VISTAKON® (narafilcon A) Contact Lens	VISTAKON® (narafilcon B) Contact Lens
Material USAN Name	narafilcon A	narafilcon 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® (narafilcon A) Contact Lens – K073485		**Subject Device VISTAKON® (narafilcon 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: $10^{-11}(cm^2/sec)(ml\ O_2/ml \times mmHg)$

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® (narafilcon 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.

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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® (narafilcon 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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® (narafilcon 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

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,

Kesia Alexander

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® (narafilcon B) Contact Lens Visibility Tinted, with UV Blocker

Indications for Use:

The VISTAKON® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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 Warburton

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

510(k) Number K100349

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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® (narafilcon 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

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Sincerely yours,

Kesia Alexander

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® (narafilcon B) Contact Lens Visibility Tinted, with UV Blocker

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The VISTAKON® (narafilcon 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.

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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 Waburton

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

510(k) Number K100349

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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) CONTAC

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. Pleaseremember 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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) CONTAC

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.

[redacted]

72

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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.

FEB 12 2010

Received

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® (narafilcon 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® (narafilcon B) Contact Lens

The lenses are made from a modified lens material, narafilcon 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® (narafilcon B) Contact Lens
For Single Use Daily Wear Only

Volume 1 of 3

February 8, 2010

Table of Contents

	Page Number
VOLUME 1	
1 - Medical Device User Fee Cover Sheet	2
2 - CDRH Premarket Review Submission Cover Sheet	5
- ClinicalTrials.gov	14
- Reviewer Checklists	16
3 – 510(k) Cover Letter	31
4 - Indications for Use Statement	33
5 - 510(k) Summary	35
6 - Truthful and Accuracy Statement	42
7 – Class III Summary and Certification	44
8 - Financial Certification	45
9 - Declaration of Conformity and Summary Reports	47
10 - Executive Summary	64
11 - Device Description	71
12 - Substantial Equivalence Discussion	82
13 – Proposed and Predicate Labeling	88
14 - Sterilization and Shelf Life	92
15 – Biocompatibility	97
16 – Software	102
17 - Electromagnetic Compatibility and Electrical Safety	103
18 - Performance Testing – Bench	104
19 - Performance Testing – Animal	107
20 - Performance Testing – Clinical	108
21 – Other	112
Attachment A – Engineering Drawings	A
Attachment B – Manufacturing Flow Chart	B
Attachment C – Shelf Life Protocol	C
Attachment D – MSDS	D
Attachment E – Biocompatibility Reports	E
Attachment F – USAN	F
Attachment G – Proposed Labeling	G
VOLUME 2	
Attachment H – Clinical Study Report	H
VOLUME 3	
Attachment H – Clinical Study Report (continued)	H-294
Attachment I – Standard Data Summary Reports	I

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/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

VISTAKON
7500 CENTURION PARKWAY SUITE 100
JACKSONVILE 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:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER
3.2 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] 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?
[X] 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.)
[ ] 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.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] 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).

[ ] YES [X] 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

00013-00346

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

OD

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. (b)(4),(b)(6)
Check Date 01/20/2010
Check Amount (b)(4),(b)(6)
Vendor Number (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)(
				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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

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

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify):*

Change in lens material.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LPL	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached

☐ 510 (k) statement

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) (narafilcon A) Contact Lens	1	Johnson & Johnson Vision Care, Inc.
2	K962804	2	VISTAKON(R) (etafilcon 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) (narafilcon 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	C.F.R. Section *(if applicable)*	Device Class
LPL	21 CFR 886.5925	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
Ophthalmic Devices		

Indications *(from labeling)*

Provided on the following page.

Indications for Use

The VISTAKON® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 1057985	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ 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 1, Regulatory Affairs	Contact E-mail Address: cdillon9@its.jnj.com	

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 9617710	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ 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 1, Regulatory Affairs	Contact E-mail Address: cdillon9@its.jnj.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number:	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ 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 (narafilcon B) Contact Lens

VISTAKON (etafilcon A) Cotnact 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	**Y**				**72, F**
b. Modified lens falls into one of the lens groups	**Y**				**72**
c. Side-by-side comparison of physiocochemical properties of proposed lens compared with predicate device	**Y**				**106**
d. If lens is an RGP lens, modulus, toughness, and flexural strength are in the ranges of approved lenses in that lens group	**N/A**				**N/A**
e. Appropriate clinical performance data which demonstrate SE	**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 B. Bioburden Method	**X**				**93**
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" PDA Technical Monograph No. 1: "Validation of Steam Sterilization"		**X**	**X**		**93**

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? 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) 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 • 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 tinteded 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**
a. If the applicant has a previously approved PMA, PMA supplement, or an SE 510(k) for daily wear RGP lenses but does not have CDRH clearance for adding finishing laboratories, OR, b. If the applicant does not 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).					
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**
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, 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.					

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**
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, 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. 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.					

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
a. If the applicant has a previously approved PMA, PMA supplement, or an SE 510(k) for daily wear RGP lenses but does not have CDRH clearance for the incorporation of a listed color additive in the contact lens material, OR 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.					
2. If the 510(k) meets the criteria for 1(a) or 1(b), did the applicant provide:		X	N/A		N/A
a. a COMPLETE 510(k) application as specified in the PREMARKET NOTIFICATION (510(k)) GUIDANCE DOCUMENT FOR DAILY WEAR CONTACT LENSES, and, 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.					
If a daily wear contact lens manufacturer deviates 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:					
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, 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					
If yes (and also after clearance has been received for a daily wear contact lens):					
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.					
If a daily wear contact lens manufacturer deviates 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.					

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® (narafilcon 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® (narafilcon B) Contact Lens

The lenses are made from a modified lens material, narafilcon 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® (narafilcon B) Contact Lens Visibility Tinted, with UV Blocker

Indications for Use:

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

Indication, Wear Schedule

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

Note: The VISTAKON® (narafilcon A) Contact Lens has not been marketed in the United States.

Continued on next page

510(k) Summary, Continued

Description of Device

- The VISTAKON® (narafilcon 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® (narafilcon 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® (narafilcon 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% narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon B) Contact Lenses are compared to the characteristics of the predicate device, VISTAKON® (narafilcon A) Contact Lens, in the following tables.

Material Comparison		
	Predicate Device	**Subject Device**
Product Name	VISTAKON® (narafilcon A) Contact Lens	VISTAKON® (narafilcon B) Contact Lens
Material USAN Name	narafilcon A	narafilcon 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® (narafilcon A) Contact Lens – K073485		**Subject Device** VISTAKON® (narafilcon 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} $(cm^2/sec)(ml\ O_2/ml \times mmHg)$

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® (narafilcon 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® (narafilcon 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 Date
Project Leader
Regulatory Affairs

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

Section 7: Class III Summary and Certification

This section is not applicable.

Section 8: Financial Certification or Disclosure Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: August 31, 2012

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 (b)(6)	DATE *(mm/dd/yyyy)* 01/27/2010

Paperwork Reduction Act Statement

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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)

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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)	
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: _____

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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	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

See Attachment I for documentation of extent of conformance.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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DESCRIPTION

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Paperwork Reduction Act Statement

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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]

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)

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Department of Health and Human Services
Food and Drug Administration

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EXTENT OF STANDARD CONFORMANCE
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STANDARD TITLE

(b)(4)

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TYPE OF DEVIATION OR OPTION SELECTED *

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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	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

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DESCRIPTION

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

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)

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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	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

See Attachmet I for documentation of extent of conformance

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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DESCRIPTION

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)

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FDA Recognition number [3] # _____		
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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).	☐	☑
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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] ?	☐	☐
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EXTENT OF STANDARD CONFORMANCE
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STANDARD TITLE
(b)(4)

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N/A	N/A	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

See Attachment I for Certification to ISO 13485 by TUV SUD America Inc.

DESCRIPTION

Scope includes: Design, Development, Production and Distribution of Sterilization Process Indicators and Laboratory Services

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

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JUSTIFICATION

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Section 10: Executive Summary

10.0 Executive Summary

Use of Terms

Subject device is used interchangeably with:

- VISTAKON® (narafilcon B) Contact Lenses Visibility Tinted with UV Blocker
- VISTAKON® (narafilcon B) Contact Lens

Throughout the reports and other documentation provided as part of the 510(k) the product may be referred to as:

- narafilcon B
- narafilcon [redacted] (b)(4)
- VISTAKON® Investigational Contact Lenses (narafilcon [redacted] (b)(4)

Predicate Device(s)

Material

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

Indication, Wear Schedule

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

Note: The VISTAKON® (narafilcon A) Contact Lens has not been marketed in the United States.

Continued on next page

10.0 Executive Summary, Continued

Description of Device

- The VISTAKON® (narafilcon 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® (narafilcon 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® (narafilcon 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% narafilcon B and 48% water by weight when hydrated and stored in the buffered saline solution.

Continued on next page

10.0 Executive Summary, Continued

Indications for Use

Lens Design	Indication
Spherical	The VISTAKON® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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

10.0 Executive Summary, Continued

Technological Characteristics

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

Material Comparison		
	Predicate Device	**Subject Device**
Product Name	VISTAKON® (narafilcon A) Contact Lens	VISTAKON® (narafilcon B) Contact Lens
Material USAN Name	narafilcon A	narafilcon 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® (narafilcon A) Contact Lens – K073485		**Subject Device** VISTAKON® (narafilcon 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: $10^{-11}(cm^2/sec)(ml\ O_2/ml \times mmHg)$

Continued on next page

10.0 Executive 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® (narafilcon 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

10.0 Executive 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® (narafilcon 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 11: Device Description

11.1 General

Topic	See Page
Device Name	72
Common or Usual Name	72
Establishment Registration Number	72
Device Classification	72
Performance Standards	72
Material	72
Predicate Devices	72
Change or Modification to an Existing Device	72

11.2 Product Information

Topic	See Page
Device Description	73
Actions	73
Indications for Use	74
Lens Material	75
Chemistry Components	76
Engineering Drawings	77
Design Performance	77
Finished Lens Parameters	77
Physical Appearance	78
Physiochemical Properties	79

11. 3 Manufacturing

Topic	See Page
Manufacturing Process	80
Manufacturing Flow Diagram	80
Manufacturing Information	80
Polymerization and Annealing Conditions	81
Sterilization Method	81
Visibility Tinting Process	81
Packaging Materials and Methods	81

11.1 General

Device Name	VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV blocker.
Common Name	Soft Contact Lens
Establishment Registration Numbers	1057985 – United States Facility 9617710 – Ireland Facility
Device Classification	Class II, 21 CFR 886.5925 (b) (1).
Performance Standards	None established under Section 514 of the Act.
Material	On February 8, 2010, Johnson & Johnson Vision Care, Inc. (JJVCI) received formal notification of adoption of the name **narafilcon B** (USAN XX-48) for the soft contact lens material described in this document. A copy of the United States Adoption Names Council (USAN) notification letter is included in **Attachment E**.
Predicate Devices	The subject device is substantially equivalent to the predicate devices, VISTAKON® (narafilcon A) Contact Lens (material and parameters) and 1-DAY ACUVUE® (etafilcon A) Brand Contact Lens (indications for use and wear schedule). Note: The VISTAKON® (narafilcon A) Contact Lens has not been introduced into the United States market.
Change or Modification to an Existing Device	This notification is for a modified lens material (modified USAN) that conforms to the requirements for FDA Group I. This notification supports the assessment that the modified contact lens material, narafilcon B, is substantially equivalent to existing low water soft hydrophilic contact lenses.

11.2 Product Information

Device Description

- The VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV blocker is available as a spherical lens, a multifocal lens, a toric lens and a multifocal-toric lens.
- The lenses are made of a silicone hydrogel material containing an internal wetting agent.
- The VISTAKON® (narafilcon B) Contact Lens may be 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® (narafilcon 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% narafilcon B and 48% water by weight when hydrated and stored in the buffered saline solution.

Actions

In its hydrated state, the VISTAKON® (narafilcon B) Contact Lens Visibility Tinted, with UV blocker, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

Continued on next page

11.2 Product Information, Continued

Indications for Use

Lens Design	Indication
Spherical	The VISTAKON® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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

11.2 Product Information, Continued

Lens Material

- The lens material, narafilcon B, is a copolymer of 2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester polymer with Poly[oxy(dimethylsilylene)], **α**-(butyldimethylsilyl)-**ω**-[[[3-[2-hydroxy-3-[(2-methyl-1-oxo-2 propenyl)oxy]propoxy]propyl]dimethylsilyl]oxy]- and 2-propenamide, N,N-dimethyl and 2-pyrrolidinone, 1- ethenyl-, homopolymer and 2-Propenoic acid, 2-methyl-, oxybis(2,1-ethanediyloxy-2,1-ethanediyl) ester

- The VISTAKON® (narafilcon 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 composition of the lens is 52% narafilcon B and 48% water by weight when hydrated and stored in the buffered saline solution.

Continued on next page

11.2 Product Information, Continued

Chemical Composition

The chemical composition for the narafilcon B contact lens material is listed below with reference to mole and weight percentages. The composition is fixed for narafilcon B (b)(4) of nominal.

Material	Function	Purity (%)	Wt (%)	Mole (%)
(b)(4)				

Continued on next page

11.2 Product Information, Continued

Engineering Drawings

Representative engineering drawings for the spherical, multifocal, toric and multifocal-toric lens designs are provided in **Attachment A**.

(b)(4)

Design Performance

The data for the pre-clinical and clinical performance of the lens material are equally applicable to all lens designs presented in this notification.

Finished Lens Parameters

Parameters may be confirmed either through finished lens testing, in-process testing or process controls.

Parameter	Tolerance
Diameter	Label Claim ± (b)(4)
Center Thickness	Label Claim ±
Base Curve	Label Claim ±
Power: 0 ≤ D ≤ ±10.00 ± 10.00 < D ≤ ± 20.00	Label Claim ± Label Claim ±

The multifocal lens and the multifocal-toric lens have the additional parameters of:

Parameter	Tolerance
Multifocal ADD powers	Label Claim ± (b)(4)

The toric lens and the multifocal-toric lens have the additional parameters of:

Parameter	Tolerance
Axis	(b)(4
Cylinder: D ≤ 2 D ±2 D < D ≤ ± 4 D D < ±4 D	Label Claim ± (b)(4) Label Claim ± Label Claim ±

Note: The tolerances described above are consistent with (b)(4 (b)(4) to the extent discussed in the Standards Data Summary Report provided in **Attachment I**. They are the same as those identified in K073485.

Continued on next page

11.2 Product Information, Continued

Physical Appearance

The lenses will be (b)(4) inspected by either (b)(4) or by (b)(4) for the physical appearance of the lenses. The processes and (b)(4) have been validated to result in release of product that is equivalent to or better than (b)(4) for visual attributes.

When shape and appearance is evaluated in accordance with (b)(4) the lens must meet the following standards:

1. (b)(4)
2. (b)(4)

Continued on next page

11.2 Product Information, Continued

Physicochemical Properties Ranges

Specification ranges for the VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV Blocker, are summarized in the table below:

Property	Specification
Water Content, %	(b)(4)
Refractive Index @ 20°C	
*Dk, edge corrected	
Color	
Light Transmittance @ 380 - 780 nm, %	
Light Transmittance @ 316 - 380 nm, %	
Light Transmittance @ 280 - 315 nm, %	
Tensile Strength, psi	
Elongation, %	
Modulus, psi	
Toughness, in lb/in^3	
Dynamic Contact Angle (°), (DCA)	

*Dk units: 10^{-11} (cm^2/sec)(ml O_2/ml x mmHg)

Section 11.3 Manufacturing Information

Manufacturing Process

(b)(4)

Manufacturing Flow Diagram

The manufacturing flow diagram is presented in **Attachment B**.

Manufacturing Information

(b)(4)

All lenses are manufactured in full compliance with the 21 CFR 820 Quality System Regulations.

Note: The manufacturing process described above is the same as currently identified in K073485, with the exception for chemical composition that is identified in this notification.

Continued on next page

Section 11.3 Manufacturing Information, Continued

Polymerization and Annealing Conditions

The polymerization conditions may vary with lens profile. The approximate polymerization ranges for the VISTAKON® (narafilcon B) Contact Lens material are:

- Time
- Temperature
- Wattage

(b)(4)

Sterilization Method

The sterilization method is moist heat sterilization.

The sterilization method and cycle has been shown to be effective for sterilizing the VISTAKON® (narafilcon B) Contact Lens when packaged in sealed polypropylene blisters containing buffered saline packing solution with methyl ether cellulose.

Refer to **Section 14** for further discussion of sterilization of the subject device.

Note: The sterilization method described above is the same as the process identified in K073485.

Visibility Tinting Process

(b)(4)

Note: The tinting process described above is the same as the process identified in K073485.

Packaging Materials and Methods

The VISTAKON® (narafilcon B) Contact Lens is packaged in buffered saline solution with methyl ether cellulose solution in a (b)(4) blister heat sealed to (b)(4) (b)(4) lidstock.

Note: The packaging system described above is used by JJVCI for all marketed contact lens products. Reference (b)(4) (b)(4)

Section 12: Substantial Equivalence Discussion

Contents

This section contains the following information:

Section	Topic	See Page
12.1	FDA 510(k) Substantial Equivalence Decision Making Process	83
12.2	Substantial Equivalence Discussion	85

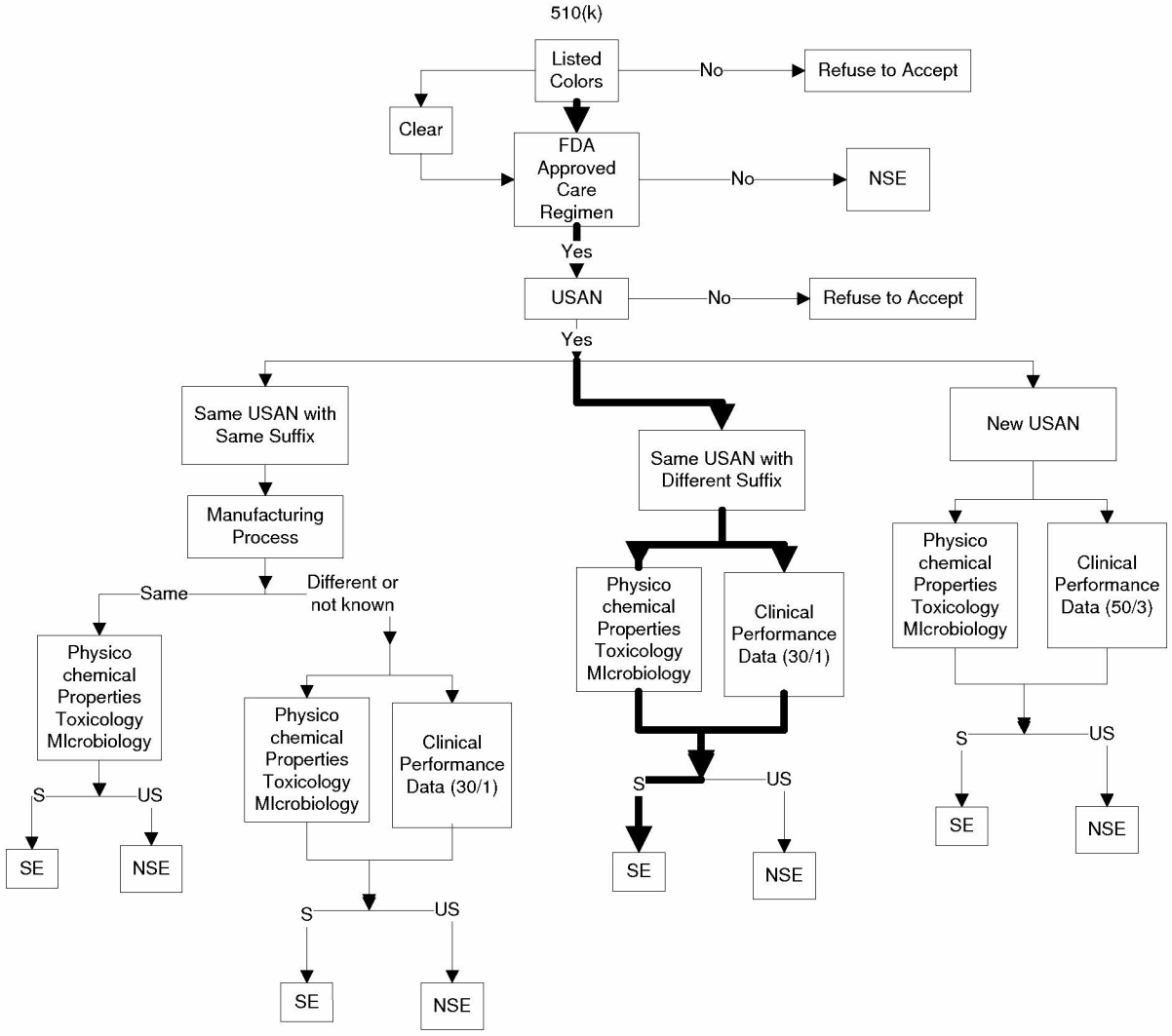
12.1 FDA 510(k) Substantial Equivalence Decision Making Process

Introduction

The FDA 510(k) Substantial Equivalence Decision Making Process flowchart has been provided on the following page to support the decision that the VISTAKON® (narafilcon B) Contact Lens is substantially equivalent to the predicate devices.

Continued on next page

12.1 FDA 510(k) Substantial Equivalence Decision Making Process, Continued



12.2 Substantial Equivalence Discussion

Substantially Equivalent

Substantially equivalent as used in this notification is intended to be a determination of substantial equivalence under the Federal Food, Drug and Cosmetic Act, and means that the product can be marketed without premarket approval or reclassification. Such a determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits or other patent matters.

Predicate Device(s)

Predicate devices are used interchangeably with:

Material

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

Indication, Wear Schedule

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

Continued on next page

12.2 Substantial Equivalence Discussion, Continued

Material Comparison		
	Predicate Device	**Subject Device**
Product Name	VISTAKON® (narafilcon A) Contact Lens	VISTAKON® (narafilcon B) Contact Lens
Material USAN Name	narafilcon A	narafilcon 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® (narafilcon A) Contact Lens – K073485		**Subject Device** VISTAKON® (narafilcon 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

*Dk units: $10^{-11}(cm^2/sec)(ml\ O_2/ml \times mmHg)$

Continued on next page

12.2 Substantial Equivalence Discussion, Continued

Indications for Use Comparison			
	Predicate Devices		Subject Device
	VISTAKON® (narafilcon A) Contact Lens **K073485**	1·DAY ACUVUE® Brand (etafilcon A) Contact Lens **K962804**	VISTAKON® (narafilcon B) Contact Lens **Unknown**
Spherical - Intended Use	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.	Indicated for daily wear single use for the correction of refractive ametropia (myopia hyperopia, and presbyopia) in aphakic or non-aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.	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 - Intended Use	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.	Indicated for daily wear single use for the correction of distance and near vision in presbyopic, aphakic or non-aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less.	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 - Intended Use	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.	Indicated for daily wear single use for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D or less of astigmatism	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-Intended Use	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.	Indicated for daily wear single use for the correction of distance and near vision in presbyopic aphakic or non-aphakic persons with non-diseased eyes who may have 10.00D of astigmatism or less.	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.

Section 13: Proposed and Predicate Labeling

13.0 Proposed and Predicate Device Labeling

Proposed Device Labeling

Proposed labeling for the VISTAKON® (narafilcon B) contact lens is presented in **Attachment G**.

The subject device is the VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV Blocker.

A single Package Insert and Fitting and Patient Management Guide is provided combining the spherical, multifocal, toric, and toric-multifocal designs of the product. This document contains information pertaining to daily wear single-use only wear schedule.

A Patient Instruction Guide is provided for daily wear single use only schedule.

Continued on next page

13.0 Proposed and Predicate Device Labeling, Continued

Subject Device Intended Use Statements

Lens Design	Indication
Spherical	The VISTAKON® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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

13.0 Proposed and Predicate Device Labeling, Continued

Predicate Device Labeling	The predicate for the labeling is the VISTAKON® (narafilcon A) Contact Lens. The labeling is consistent with that cleared by FDA in K073485.

Section 14: Sterilization and Shelf-Life

14.0 Sterilization and Shelf Life

Sterilization Method

(b)(4)

Note: The same method of sterilization utilized for the VISTAKON® (narafilcon B) contact lens is utilized for all currently marketed VISTAKON® contact lenses.

Sterilization Validation Method

By following the requirements of (b)(4)

(b)(4)

Continued on next page

14.0 Sterilization and Shelf Life, Continued

Minimum SAL

Johnson & Johnson Vision Care, Inc. will use a validated moist heat sterilization cycle that will assure a minimum sterility assurance level (SAL) of 10^{-6}.

Description of Packaging

The VISTAKON® (narafilcon B) Contact Lens is packaged in a (b)(4) blister sealed to a (b)(4) overlay.

Note: This is the same primary packaging system used to maintain the sterility of all VISTAKON® marketed contact lens products. Please refer to K073485.

Shelf Life Expiration Dating

Shelf life stability testing for the VISTAKON® (narafilcon B) Contact Lens was generated according to the protocol found in **Attachment C**. (b)(4)

(b)(4) e. Future extensions of the expiry date will be based on the Shelf-Life Protocol provided in **Attachment C.**

The subject device utilizes a packaging system and materials that were previously cleared in K073485. The package has been previously demonstrated to maintain the sterility of the contents for at leas (b)(4) years. This feature of the package is independent of lens formulation. No additional sterility testing is required.

Plastics toxicology testing recommended in May 1994 Guidance Document for Daily Wear Lenses will also be conducted if the packaging materials are changed to new materials which have not been previously tested.

The Shelf Life protocol for this product is provided in **Attachment C.**

(b)(4)

Continued on next page

14.0 Sterilization and Shelf Life, Continued

Lot #	(b)(4)	(b)(4)

Continued on next page

CONFIDENTIAL

14.0 Sterilization and Shelf Life, Continued

Lot #	(b)(4)	(b)(4)

CONFIDENTIAL

Section 15: Biocompatibility

Contents

This Biocompatibility Section contains the following topics:

Section	Topic	See Page
15.1	Material Safety Data Sheets	98
15.2	Toxicology Testing – Lens Material	99
15.3	Toxicology Testing – Packaging Materials	101

15.1 Material Safety Data Sheets

MSDSs

The material safety data sheet for the chemical components of the narafilcon B contact lens material are included in **Attachment D.**

Continued on next page

15.2 Toxicology Testing – Lens Material

Toxicology Lens Materials

Discussion:

Toxicology testing was conducted for the VISTAKON® (narafilcon A) Contact Lens (reference K073485 cleared on March 3, 2008).

Based on the following similarities between the narafilcon A and narafilcon B lens materials, the narafilcon A testing is considered applicable to the narafilcon B lens material.

- (b)(4)

In addition, the following verification tests were conducted to demonstrate that the lens is non-irritant and non-toxic:

- (b)(4)

Conclusion:

Based on the discussion above, it can be concluded that the narafilcon B lens material and/or extracts are non-toxic, non-irritating and non-sensitizing under the experimental conditions.

A summary of the results of the testing with the narafilcon B lenses is provided on the following page. Copies of the narafilcon B reports are provided in **Attachment E.** The narafilcon A reports are available in **K073485 Attachment E.**

Continued on next page

15.2 Toxicology Testing – Lens Material, Continued

Test	Summary/Conclusion
(b)(4)	

Continued on next page

15.3 Toxicology Testing – Packaging Material

Toxicology Packaging Materials

The VISTAKON® (narafilcon B) contact lens is packaged in a (b)(4) blister sealed to a (b)(4) overlay. This is the same primary packaging system that is used by Johnson & Johnson Vision Care, Inc. for other marketed contact lens products.

In accordance with the (b)(4) (b)(4) the following toxicology testing has previously been conducted and submitted to FDA on the plastic packaging materials:

- (b)(4)

Based on the results of the tests conducted, it has been determined that the packaging components do not contain any leachable materials that could be considered cytotoxic or an irritant either systemically or to ocular tissue, and therefore, are considered suitable for use as packaging materials for contact lenses. Please refer to (b)(4) (etafilcon A).

Section 16: Software

This section does not apply as the medical device does not contain any software.

Section 17: Electromagnetic Compatibility and Electrical Safety

This section does not apply as the device does not include an electronic component.

Section 18: Performance Testing - Bench

Introduction

The Bench Testing section contains the following for the VISTAKON® (narafilcon B) Contact Lens:

Section	Topic	See Page
18.1	Leachability	105
18.2	Side-by-Side Comparison	106

18.1 Leachability

Leachability	(b)(4)

18.2 Side by Side Comparison

Side by Side Comparison

A side-by-side comparison of the physical and optical properties of the VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV Blocker (subject device) to the VISTAKON® (narafilcon A) Contact Lens (predicate device).

Property	Predicate Device, measured (SD)	Predicate Device, labeled	Subject Device, measured (SD)	Subject Device, labeled
Water Content, %	47 n=9 (0.4)	46	48 n=9 (0.1)	48
Refractive Index @ 20°C	1.40 n=6 (0.00)	1.41	1.41 n=6 (0.00)	1.41
Dk*, edge corrected	96 n=4 (NA)	100	52 n=4 (NA)	55
Color	Blue n=1	Blue	Blue n=1	Blue
Light Transmittance @ 380-780nm, %	97.29 n=5 (0.30)	94 +/- 5%	96.1 n=5 (0.9)	94 +/- 5%
Light Transmittance @ 316-380nm, %	3.48 n=5 (0.21)	<10 %	3.7 n=5 (0.5)	<10 %
Light Transmittance @ 280-315nm, %	0.01 n=5 (0.00)	<1 %	0.1 n=5 (0.0)	<1 %
Tensile Strength, psi	94 n=12 (16)	NA	87 n=12 (31)	NA
Elongation, %	217 n=12 (53)	NA	190 n=12 (75)	NA
Modulus, psi	104 n=12 (10)	NA	109 n=12 (10)	NA
Toughness, (in lb/in^3)	116 n=12 (44)	NA	99 n=12 (69)	NA
Dynamic Contact Angle, °	57 n=5 (4)	NA	54 n=5 (10)	NA
Base Curve, mm	8.53 n=10 (0.04)	8.5	8.49 n=8 (0.03)	8.5
Diameter, mm	14.26 n=10 (0.03)	14.2	14.19 n=8 (0.02)	14.2
Power, diopters	-0.92 n=10 (0.04)	-1.00	-0.98 n=8 (0.03)	-1.00
Center Thickness, mm	0.085 n=10 (0.007)	NA	0.086 n=8 (0.004)	NA

*Dk units: 10^{-11}(cm^2/sec)(ml O_2/ml x mmHg)

Section 19: Performance Testing – Animal

Animal testing has not been conducted with the VISTAKON® (narafilcon B) Contact Lens. This section is not applicable.

Section 20: Performance Testing - Clinical

20.0 Pivotal Clinical Study

Introduction

The following information regarding the Pivotal Clinical Study is provided in this section:

Topic	See Page
USAN Name Designation	110
Objective	110
Design	110
Population	110
Study Period	110
Lenses	111
Findings	111
Clinical Study Report	111

Continued on next page

20.0 Pivotal Clinical Study, Continued

USAN Name

On February 8, 2010, VISTAKON® received formal notification of adoption of the name **narafilcon B** (USAN XX-48) for the soft contact lens material described in this document. A copy of the United States Adoption Names Council (USAN) notification letter is included in **Attachment F**.

The USAN name for the predicate device lens material used in the pivotal clinical study is **etafilcon A**.

Objective

The objective of the study was to show that VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV Blocker for Daily Wear is at least substantially equivalent to the control lens, 1·DAY ACUVUE® (etafilcon A) Brand Contact Lenses. There was a ratio of 1 to 1 between the test lens and the control respectively. Adverse reactions, keratometry changes, reasons for discontinuation, and the number and reasons for unscheduled lens replacements were monitored and evaluated.

Design

In accordance with the (b)(4) (b)(4), the study was a one-month (b)(4) (b)(4) design. All lenses were worn daily wear (less than 24 hours while awake and then disposed).

Population

- A total of 48 subjects (96 eyes) were enrolled at (b) different investigator sites.
- (b)(4)

Study Period

The study was conducted between (b)(4)

Continued on next page

20.0 Pivotal Clinical Study, Continued

Lenses

The following lenses were evaluated during the investigation:

Lens Characteristic	VISTAKON® (narafilcon B) Contact Lens	1·DAY ACUVUE® (etafilcon A) Contact Lens
Manufacturer:	JJVCI	JJVCI
Base Curve:	8.5mm	8.5mm
Diameter:	14.2mm	14.2mm
Replacement Schedule:	Single Use	Single Use
Wear Schedule:	Daily Wear (less than 24 hours while awake)	Daily Wear (less than 24 hours while awake)
Powers:	(b)(4)	
Material / Tint:	narafilcon B / blue visibility tint	etafilcon A / blue visibility tint
UV Blocking:	Yes (Class I)	Yes (Class II)

Findings

The VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV Blocker was found for its intended use to be as substantially equivalent to the 1·DAY ACUVUE® (etafilcon A) Contact Lens clinically.

Clinical Study Report

The full clinical study report is found in **Attachment H**. A copy of the IRB approved protocol is included as an appendix to the report.

Section 21: Other

This section does not apply.

Attachment A – Engineering Drawings

Contents

Representative engineering drawings and design descriptions are presented in this section.

Topic	See Page
Single Vision Lens	A-2
Multifocal Lens	A-3
Toric Lens	A-4
Multifocal-Toric Lens	A-5

Continued on next page

Attachment A – Engineering Drawings, Continued

Single Vision Lens

- (b)(4)
-

(b)(4)

Continued on next page

Attachment A – Engineering Drawings, Continued

Multifocal Lens

- (b)(4)
-
-
-

(b)(4)

(b)(4)

Continued on next page

Attachment A – Engineering Drawings, Continued

Toric

(b)(4)

(b)(4)

Continued on next page

Attachment A – Engineering Drawings, Continued

Multifocal-Toric Lens

- (b)(4)
-
-
-
-

(b)(4)

Attachment B - Manufacturing Flow Diagram

Contents

This section contains the VISTAKON® (narafilcon B) Contact Lens manufacturing flow diagram.

Manufacturing Process for VISTAKON® (narafilcon B) Contact Lenses

(b)(4)

Attachment C - Shelf Life Protocol

Contents

Shelf life may be established using the protocol provided on the following pages. The protocol was used to generate the data in this notification.

Continued on next page

Johnson & Johnson
Vision Care, Inc.

November 18, 2009

VISTAKON® Contact Lens and/or Package System (b)(4) Protocol

(b)(4)

Table of Contents

Topic	See Page
Introduction	3
Testing Protocol	4

Introduction

(b)(4)

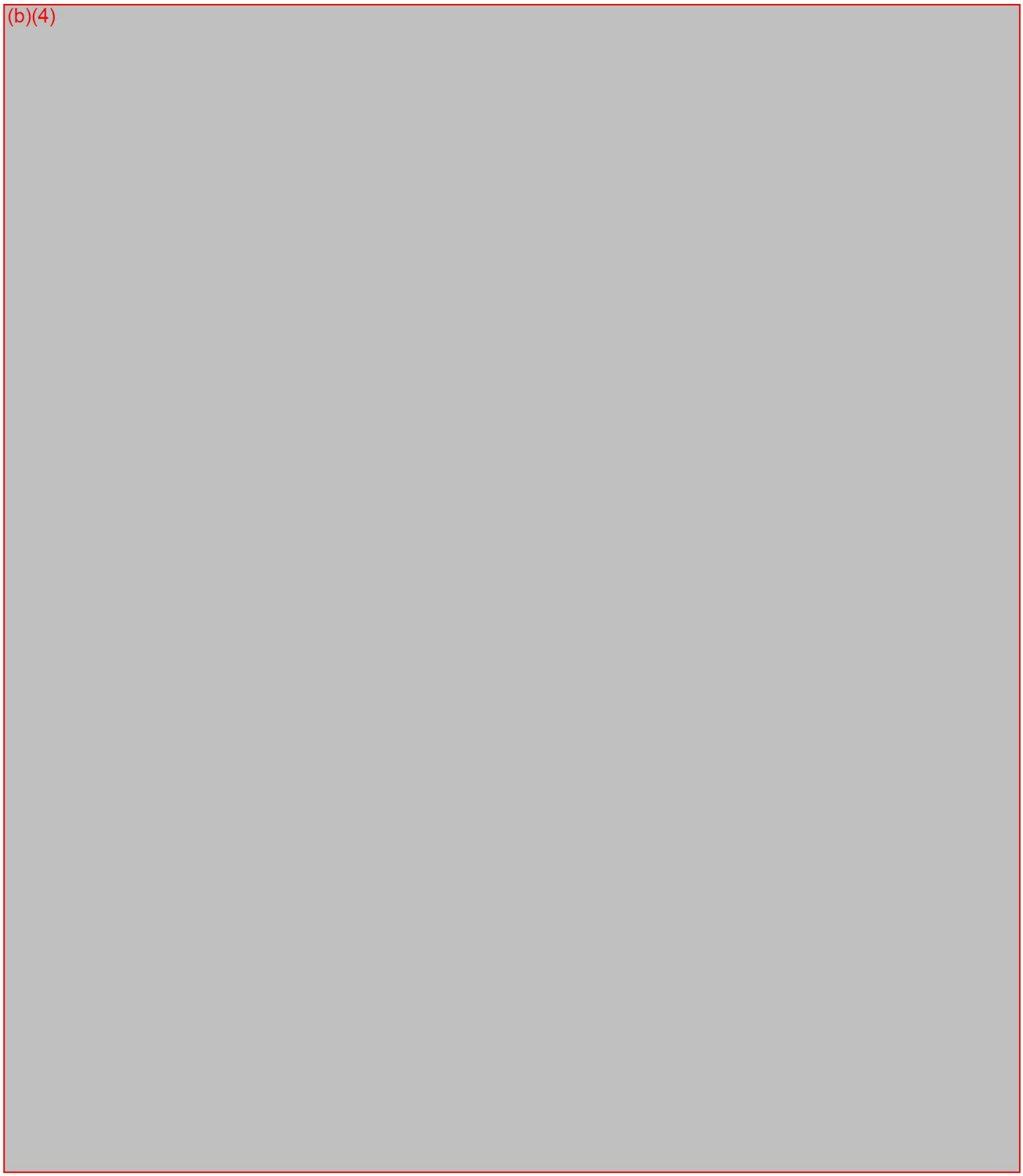
Testing Protocol

(b)(4)

Continued on next page

Testing Protocol, Continued

(b)(4)



Attachment D – MSDS

Contents

This attachment contains the material safety data sheet for the chemical components of the narafilcon B contact lens material.

Continued on next page

(b)(4),Materials

(b)(4),Materials

(b)(4),Materials

(b)(4),Materials

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Attachment E – Biocompatibility Reports

Contents

This attachment contains the following biocompatibility reports:

- (b)(4)
-

Continued on next page

(b)(4),Biocompatibility

(b)(4),Biocompatibility

(b)(4),Biocompatibility

(b)(4),Biocompatibility

(b)(4),Biocompatibility

(b)(4),Biocompatibility

(b)(4),Biocompatibility

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(b)(4),Biocompatibility

(b)(4),Biocompatibility

(b)(4),Biocompatibility

(b)(4),Biocompatibility

(b)(4),Biocompatibility

(b)(4),Biocompatibility

Attachment F – USAN

Contents

This attachment contains a copy of the USAN letter of adoption for **narafilcon B**.

Continued on next page

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January 27, 2010

Helene M. Biernacki
Research Associate USAN
USAN Council Assistant Secretary

RECEIVED
FEB 08 2010

xx-48

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

Dear Ms. Dillon,

I am pleased to inform you that the USAN Council has adopted the name ***narafilcon B*** as the USAN Modified (USANM) for Johnson & Johnson Vision Care's contact lens material.

Please review the USANM information on the enclosed adoption statement for accuracy, initial, and return the statement to me within 60 days of the date listed above along with a signed review confirmation form. Please note ***narafilcon B*** will not be published by USAN until it appears in the FDA-CDRH 510(k) database. When this occurs, the USANM information on ***narafilcon B*** will be scheduled for posting on the USAN Web site (www.ama-assn.org/go/usan). At the same time, the USANM information on ***narafilcon B*** will be submitted to the United States Pharmacopeial Convention, Inc. for publication in the *USP Dictionary of USAN and International Drug Names.*

You may mail, fax, or e-mail any changes regarding the publication of ***narafilcon B*** to me at any time before April 1, 2010.

Sincerely,

Helene Biernacki

Helene Biernacki, Research Associate
USAN Council Assistant Secretary
USAN Program

enclosure: N10/12

January 27, 2010

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

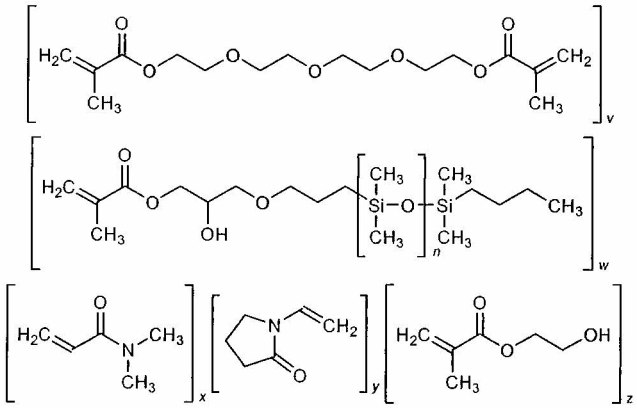
USAN (xx-48)	NARAFILCON B
PRONUNCIATION	nar" a fil' kon
INGREDIENT FUNCTION	contact lens material (hydrophilic)

CHEMICAL NAME

1. 2-Propenoic acid, 2-methyl-, 1,1'-[oxybis(2,1-ethanediyloxy-2,1-ethanediyl)] ester, polymer with α-(butyldimethylsilyl)-ω-[[[3-[2-hydroxy-3-[(2-methyl-1-oxo-2-propen-1-yl)oxy]propoxy]propyl]dimethylsilyl]oxy]poly[oxy(dimethylsilylene)], *N*,*N*-dimethyl-2-propenamide, 1-ethenyl-2-pyrrolidinone and 2-hydroxyethyl 2-methyl-2-propenoate

2. 2,2'-[oxybis(ethyleneoxy)]diethyl bis(2-methylprop-2-enoate) polymer with α-(butyldimethylsilyl)-ω-(3-{(2*RS*)-2-hydroxy-3-[(2-methylprop-2-enoyl)oxy]propoxy}propyl)poly[oxy(dimethylsilylene)], *N*,*N*-dimethylprop-2-enamide, 1-ethenylpyrrolidin-2-one and 2-hydroxyethyl 2-methylprop-2-enoate

STRUCTURAL FORMULA



MOLECULAR FORMULA	$[C_{16}H_{32}O_4Si[C_2H_6OSi]_n]_w \cdot [C_{16}H_{26}O_7]_v \cdot [C_6H_{10}O_3]_z \cdot [C_6H_9NO]_y \cdot [C_5H_9NO]_x$
CODE DESIGNATION	n/a
MANUFACTURER	Johnson & Johnson Vision Care, Inc.
WATER CONTENT (at ambient temperature (23±2°C)	48%
OXYGEN PERMEABILITY at 35°C (Dk Value)	55×10^{-11} (cm^2/s)(mL O_2/mL*mmHg) (edge & boundary corrected)
CAS REGISTRY NUMBER	909294-16-2

HMB

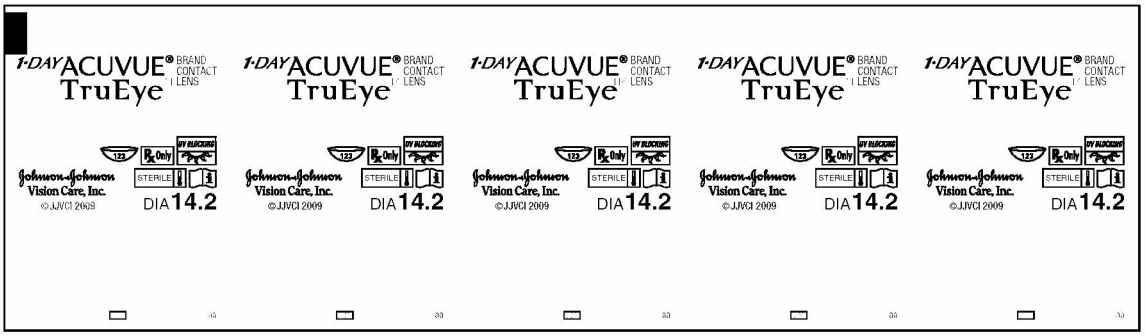
Attachment G – Proposed narafilcon B Labeling

Contents

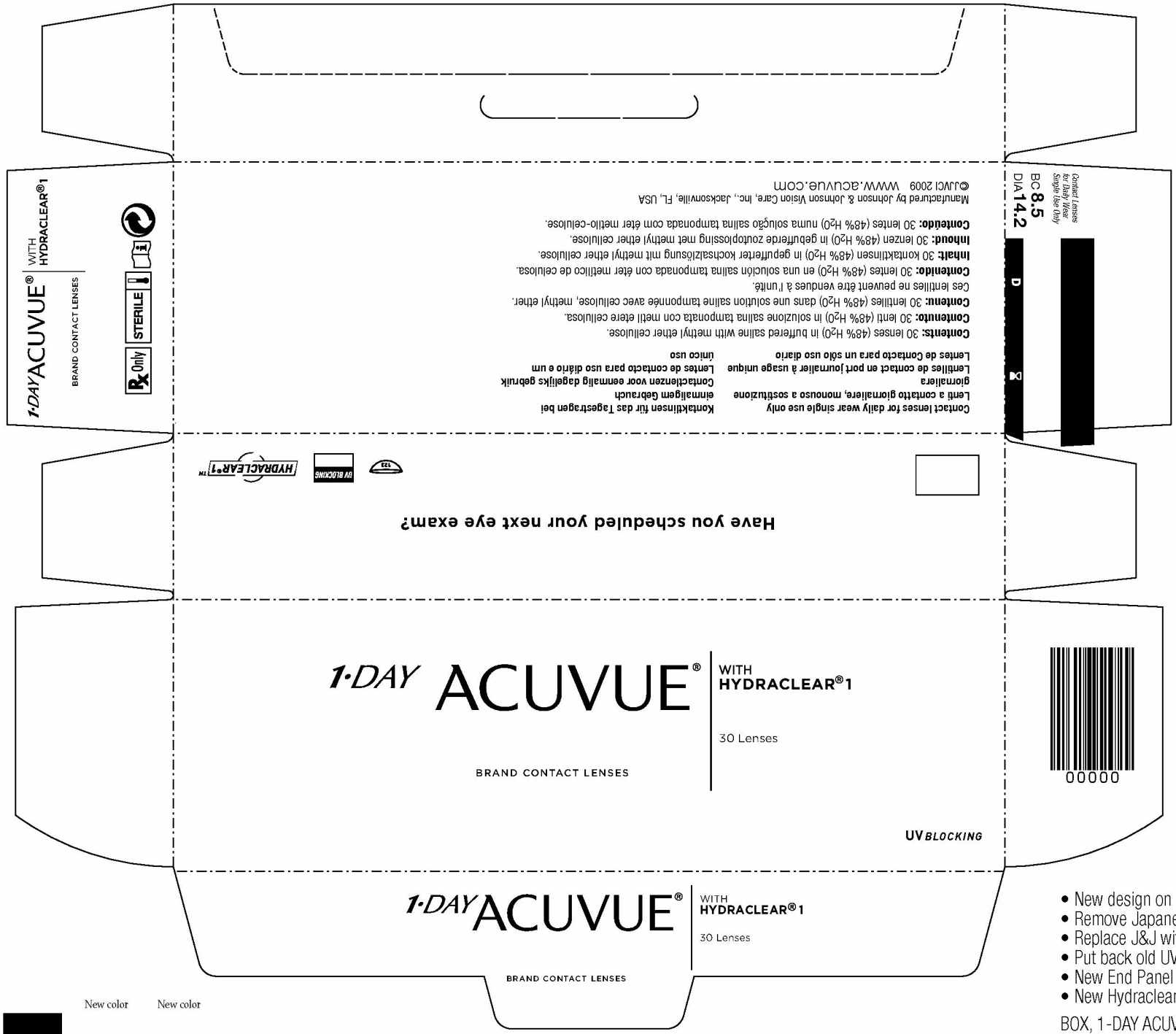
This attachment contains the following proposed labeling for the VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV Blocker:

Topic	See Page
Primary Label	G-2
Secondary Label	G-3
Package Insert and Fitting and Patient Management Guide	G-5
Patient Instruction Guide	G-30

(b)(4)


1-DAY ACUVUE® BRAND CONTACT LENS
TruEye
Johnson & Johnson
Vision Care, Inc.
©JJVCI 2009
STERILE
UV BLOCKING
DIA 14.2

(b)(4)



- New design on Non-Laser, US only
- Remove Japanese, CEmark
- Replace J&J with new UV symbol
- Put back old UV symbo on spine
- New End Panel
- New Hydraclear symbol

BOX, 1-DAY ACUVUE TruEye
Narafilcon B
8.5 30PK RX, MINUS - Face Lift
9/21/09

New color New color

INDICATES Pantone® 287C | INDICATES Pantone® 7461C | INDICATES Pantone® 2935C | INDICATES Pantone® 108C | INDICATES Pantone® Cool Gray 9C | INDICATES Pantone® 8201C (METALLIC BACKGROUND)

CONFIDENTIAL
Layout For Copy Clearance Only - Artwork has NOT been approved

Take care of your eyes.
Replace your lenses as directed.

Important Information-Have your eyes examined regularly and always follow your Eye Care Professional's instructions for the proper use and care of your lenses. Please read your *1•DAY* ACUVUE® TruEye™ Brand Contact Lenses Patient Instruction Guide for important safety information before use. Ask your Eye Care Professional for a copy of the Patient Instruction Guide or visit www.acuvue.com.

Informazioni importanti-Sottoporsi regolarmente a controlli della vista ed attenersi sempre alle istruzioni di un professionista del settore per l'uso e la cura delle lenti. Prima dell'uso, leggere il manualetto di istruzioni per il portatore *1•DAY* ACUVUE® TruEye™ Brand Contact Lenses per importanti informazioni sulla sicurezza. Chieda al suo Ottico una copia del Manualetto di Istruzioni o visiti il sito www.acuvue.com.

Informations importantes-Faites examiner vos yeux régulièrement et respectez toujours les conseils d'utilisation ainsi que les recommandations de votre spécialiste. Lire attentivement le guide d'utilisation avant tout usage de vos lentilles *1•DAY* ACUVUE® TruEye™ Brand Contact Lenses. Pour des informations complémentaires, contacter le site www.acuvue.com. Demandez un guide d'instruction porteur à votre spécialiste.

Información importante-Haga que examinen sus ojos regularmente y siga siempre las instrucciones del Profesional en el Cuidado de la Visión para el uso y cuidado apropiado de sus lentes de contacto. Antes de usar sus lentes de contacto, lea la Guia de instrucciones para el paciente *1•DAY* ACUVUE® TruEye™ Brand Contact Lenses para obtener información importante de seguridad antes de su uso. Pida a su Profesional en el Cuidado de la Visión una copia de la Guia de instrucciones del Paciente o visite www.acuvue.es.

Wichtige Hinweise-Lassen Sie Ihre Augen regelmäßig untersuchen und befolgen Sie die Anweisungen Ihres Augenarztes oder Augenoptikers in Bezug auf die richtige Benutzung und Pflege Ihrer Kontaktlinsen. Bitte lesen Sie für wichtige Sicherheitshinweise den *1•DAY* ACUVUE® TruEye™ Brand Contact Lenses Ratgeber vor dem Gebrauch der Kontaktlinsen. Fragen Sie Ihren Anpasser nach einem Exemplar des Ratgebers für Kontaktlinsenträger oder besuchen Sie uns auf www.acuvue.com.

Belangrijke informatie-Laat uw ogen regelmatig onderzoeken en houd u altijd aan de instructies van uw contactlensspecialist voor het juiste gebruik van en de juiste zorg voor de lenzen. Lees vóór gebruik het *1•DAY* ACUVUE® TruEye™ Brand Contact Lenses instructieboekje voor belangrijke informatie over veiligheid. Vraag uw contactlensspecialist naar het instructieboekje voor contactlensdragers of bezoek www.acuvue.com.

Informações Importantes-Faça regularmente um exame aos seus olhos e siga sempre as instruções do seu Especialista de Visão para o uso e manutenção correctas das suas lentes de contacto. Antes de usar, leia o Manual de Instruções do Paciente *1•DAY* ACUVUE® TruEye™ Brand Contact Lenses para obter informações importantes de segurança. Peça ao seu Especialista de Visão um Guia de Instruções do Paciente ou visite-nos no site: www.acuvue.com.br.

Protected by one or more of the following U.S. patents US 5697495, US 6270218, US 6367929, US 6822016, USD 485064, USD 401762

(b)(4)

(b)(4)

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CONFIDENTIAL

• Remove US6943203

PACKAGE INSERT
&
FITTING AND PATIENT MANAGEMENT GUIDE

IMPORTANT: Please read carefully and keep this information for future use.

This Package Insert is intended for the Eye Care Professional, but should be made available to patients upon request. The Eye Care Professional should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

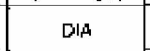
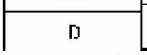
VISTAKON® (narafilcon B) Contact Lenses (Spherical)
VISTAKON® (narafilcon B) Contact Lenses (Multifocal)
VISTAKON® (narafilcon B) Contact Lenses (Toric)
VISTAKON® (narafilcon B) Contact Lenses (Multifocal-Toric)

Visibility Tinted with UV Blocker
For Single Use Daily Wear Only

VISTAKON® (narafilcon B) Contact Lenses (Spherical); VISTAKON® (narafilcon B) Multifocal Contact Lenses; VISTAKON® (narafilcon B) Toric Contact Lenses VISTAKON® (narafilcon B) Multifocal-Toric Contact Lenses; Soft (hydrophilic) Contact Lenses- Visibility Tinted with UV Blocker for Daily Wear Single Use only.

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	See Instruction Leaflet
	Use By Date (expiration date)
	Batch Code
	Sterile Using Steam or Dry Heat
	Diameter
	Base Curve
	Diopter (lens power)
	UV Blocking
	Fee Paid for Waste Management
	Peel Back Foil
	Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner
	Center Thickness
	Visibility Tinted Lens Orientation Correct Visibility Tinted Lens Inside Out
	Cylinder Power Axis
LOW	"Low" near ADD
MID	"Medium" near ADD
HIGH	"High" near ADD

Spherical Lenses For:
Myopia, Hyperopia, Phakic or Aphakic

Multifocal Lenses For:
Presbyopia, Phakic or Aphakic

Toric Lenses For:
Myopic Astigmatism, Hyperopic Astigmatism, Mixed Astigmatism, Phakic or Aphakic

Multifocal-Toric Lenses For:
Presbyopic Astigmatism , Phakic or Aphakic

CAUTION: Federal U.S.A law restricts this device to sale by or on the order of a licensed practitioner.

DESCRIPTION

The VISTAKON® (narafilcon B) Soft (hydrophilic) Contact Lenses are available as a Spherical, Multifocal, Toric or a Multifocal-Toric lens. The lenses are made of a silicone hydrogel material containing an internal wetting agent with visibility tinted UV absorbing monomer. The VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV Blocker is tinted blue using Reactive Blue Dye #4 to make the lenses 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 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

Lens Properties:

- **Specific Gravity: 1.07**
- **Refractive Index: 1.41**
- **Light Transmittance: 85% minimum**
- **Surface Character: Hydrophilic**
- **Water Content: 48%**
- **Oxygen Permeability:**

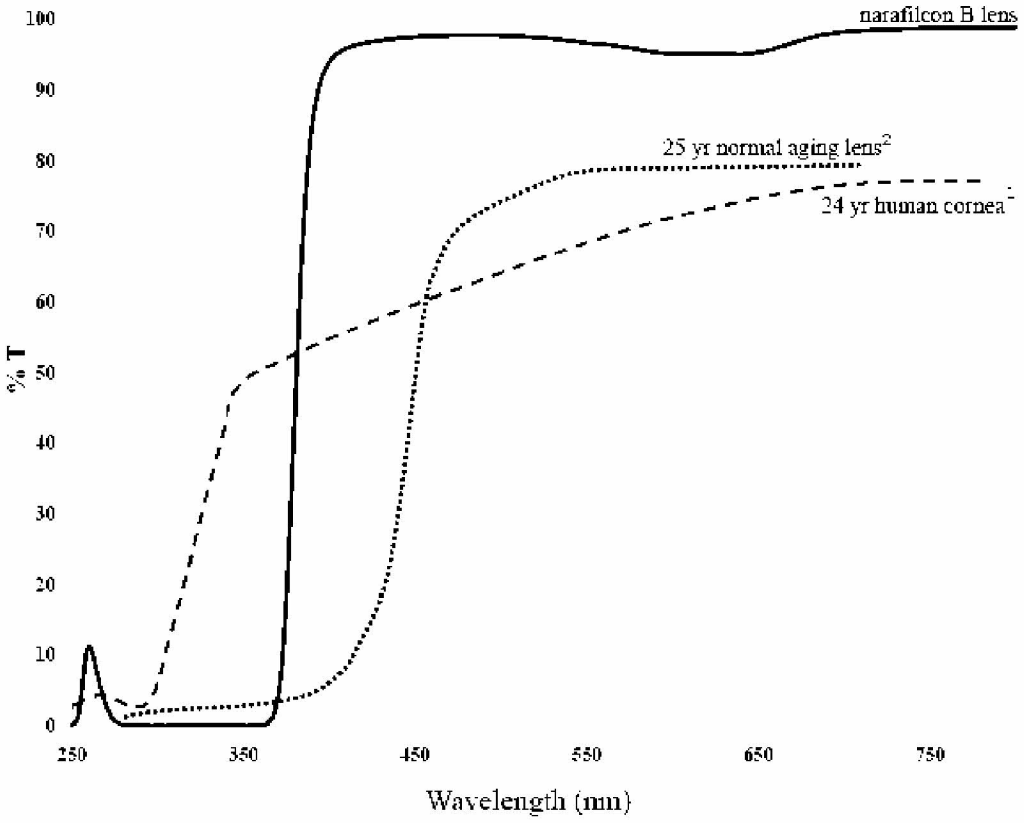
VALUE	**METHOD**
55×10^{-11} (cm^2/sec) (ml O2/ml x mm Hg) at 35°C	Polarographic edge and boundary corrected

Lens Parameters:

The VISTAKON® (narafilcon B) Contact Lenses are a hemispherical and/or hemitoric shell available within the following dimensions:

Diameter Range:	12.0mm to 15.0mm		
Center Thickness:	Low minus lens – (0.085mm)		
	Plus lens – varies with power (e.g., +3.00D: 0.170mm)		
Base Curve Range:	7.80mm to 10.00mm		
Power Range:			
	Spherical Power:	Daily Wear	-20.00D to +20.00D
	Multifocal ADD Powers:		+0.25D to +4.00D
	Multifocal-Toric ADD Powers:		+0.25D to +4.00D
	Cylinder Power:		-0.25D to -10.00D
	Axis:		2.5 ° to 180 °

Transmittance Curves
VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV Blocker, 24 yr. old human cornea and 25 yr. old human crystalline lens



* The data was obtained from measurements taken through the central 3-5mm portion for the thinnest marketed lens (-1.00D lens, 0.085mm center thickness).

1. Lerman, S., Radiant Energy and the eye, MacMillan, New York, 1980, p.58, figure 2-21
2. Waxler, M. Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.10, figure 5

WARNING: UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.

ACTIONS
In its hydrated state, the VISTAKON® (narafilcon B) Contact Lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

The transmittance characteristics are less than 1% in the UVB range of 280nm to 315nm and less than 10% in the UVA range of 316nm to 380nm for the entire power range.

Note: Long term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV blocking contact lenses help provide

protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your Eye Care Professional for more information.

INDICATIONS (USES)

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

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

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

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

Eye Care Professionals should prescribe the lenses for daily wear single use only (see "Wearing Schedule"). The lenses are to be discarded upon removal. Therefore, no cleaning or disinfection is required.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the VISTAKON (narafilcon B) Contact Lens when any of the following conditions exist:

- Inflammation or infection in or around the eye or eyelids
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
- Any previously diagnosed condition that makes contact lens wear uncomfortable.
- Severe dry eye
- Reduced corneal sensitivity (corneal hypoesthesia)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or surrounding tissues (adnexa) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated

WARNINGS
Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products, including lens cases, are essential for the safe use of these products
- Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- Studies have shown that the risk of ulcerative keratitis is greater for extended wear contact lens users than for daily wear users[1].
- When daily wear users wear their lenses overnight (outside the approved indication), the risk of ulcerative keratitis is greater than among those who do not wear them overnight.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.
- Studies have shown that the risk of ulcerative keratitis among contact lens users who smoke is greater than among non-smokers.

If patients experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, they should be instructed to immediately remove their lenses and promptly contact their Eye Care Professional. It is recommended that contact lens wearers see their Eye Care Professional routinely as directed.

[1] New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

PRECAUTIONS

Special Precautions for Eye Care Professionals:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the Eye Care Professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness and optic zone diameter.

  The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing Eye Care Professional.

- Patients who wear the VISTAKON® (narafilcon B) Contact Lenses to correct presbyopia using Monovision or patients who use the VISTAKON® Multifocal Contact Lenses or the VISTAKON® Multifocal-Toric Contact Lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Eye Care Professionals should instruct the patient to remove the lenses immediately if the eyes become red or irritated.

Eye Care Professionals should carefully instruct lens wear patients about the following care regimen and safety precautions:

Handling Precautions:

- Before leaving the Eye Care Professional's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.
- **DO NOT** use if the sterile blister package is opened or damaged.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, and wearing instructions in the "Patient Instruction Guide" for the VISTAKON® Contact Lens and those prescribed by the Eye Care Professional.
- Always handle lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens and the packing solution into the hand.
- Do not touch the lens with fingernails.

Lens Wearing Precautions:

- If the lens sticks (stops moving) on the eye, follow the recommended directions in "Care for a Sticking Lens". The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her Eye Care Professional.
- Never wear lenses beyond the period recommended by the Eye Care Professional.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the Eye Care Professional about wearing lenses during sporting activities, especially swimming and other water sports. Exposing contact lenses to water during swimming or while in a hot tub may increase the risk of eye infection from microorganisms.
- Always discard lenses worn as prescribed by the Eye Care Professional.

Lens Care Precautions:
The patient should be informed that no cleaning or disinfection is needed with daily wear single use only lenses. Patients should always dispose of lenses when removed and have replacement lenses or spectacles available.

Other Topics to Discuss with Patients:
- Always contact the Eye Care Professional before using any medicine in the eyes.
- Certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers and those for motion sickness, may cause dryness of the eye, increased lens awareness or blurred vision. Should such conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

Who Should Know That the Patient is Wearing Contact Lenses?
- Inform the doctor (Health Care Professional) about being a contact lens wearer.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

ADVERSE REACTIONS
The patient should be informed that the following problems may occur when wearing contact lenses:

- The eye may burn, sting and/or itch.
- There may be less comfort than when the lens was first placed on the eye.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers and corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.
- There may be excessive watering, unusual eye secretions, or redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, photo-phobia, or dry eyes may also occur if the lenses are worn continuously or for too long a time.

The patient should be instructed to conduct a simple 3-part self-examination at least once a day. They should ask themselves:

- How do the lenses feel on my eyes?
- How do my eyes look?
- Have I noticed a change in my vision?

If the patient reports any problems, he or she should be instructed to IMMEDIATELY REMOVE THE LENS.

If the discomfort or problem stops, the patient should then look closely at the lens.

If the lens is in any way damaged, the patient SHOULD NOT put the lens back on the eye. The patient should discard the lens and apply a new fresh lens on the eye.

If the lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, he or she should be instructed to dispose of the lens and apply a new fresh lens.

If the problem continues, the patient SHOULD NOT put the lens back on the eye but IMMEDIATELY CONSULT HIS OR HER EYE CARE PROFESSIONAL.

The patient should be instructed NOT to use a new lens as self-treatment for the problem.

The patient should be advised that when any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. He or she should be instructed to seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING GUIDELINES

I. GENERAL FITTING INSTRUCTIONS

VISTAKON® (narafilcon B) Contact Lens (Spherical)
VISTAKON® (narafilcon B) Contact Lens (Toric)
VISTAKON® (narafilcon B) Contact Lens (Multifocal)
VISTAKON® (narafilcon B) Contact Lens (Multifocal-Toric)

A. Patient Selection:

Patients selected to wear VISTAKON® (narafilcon B) Contact Lenses should be chosen based on:

- Motivation to wear lenses
- Ability to follow instructions regarding lens wear care
- General health
- Ability to adequately handle and care for the lenses
- Ability to understand the risk and benefits of lens wear.

Patients who do not meet the above criteria should not be provided with contact lenses.

B. Pre-fitting Examination

Initial evaluation of the patient should begin with a thorough case history to determine if there are any contraindications to contact lens wear. During the case history, the patient's visual needs and expectations should be determined as well as an assessment of their overall ocular, physical, and mental health.

Preceding the initial selection of trial contact lenses, a comprehensive ocular evaluation should be performed that includes, but is not limited to, the measurement of distance and near visual acuity, distance and near refractive prescription (including determining the preferred reading distance for presbyopes), keratometry and biomicroscopic evaluation.

Based on this evaluation, if it is determined that the patient is eligible to wear VISTAKON® (narafilcon B) Contact Lenses, the Eye Care Professional should proceed to the appropriate lens fitting instruction outlined below.

C. Initial Power Determination

A spectacle refraction should be performed to establish the patient's baseline refractive status and to guide in the selection of the appropriate lens power. Remember to compensate for vertex distance if the refraction is greater than ±4.00 D.

D. Base Curve Selection (Trial Lens Fitting)

For the VISTAKON® (narafilcon B) Spherical and Toric lenses, the 8.5mm/14.2mm Contact Lens should be selected for myopic patients regardless of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status. For the VISTAKON® (narafilcon B) Multifocal and Multifocal-Toric Contact Lenses, the initial lens should be selected from the currently available base curves.

A VISTAKON® (narafilcon B) trial lens should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses.

1. Criteria of a Properly Fit Lens

   A properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement to provide tear exchange under the contact lens with the blink and be comfortable. The lens should move freely when manipulated digitally with the lower lid, and then return to its properly centered position when released. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

2. Criteria of a Flat Fitting Lens

   A flat fitting lens may exhibit one or more of the following characteristics: decentration, incomplete corneal coverage (i.e., limbal exposure), excessive movement with the blink and/or edge standoff. If the VISTAKON® (narafilcon B) Contact Lens is judged to be flat fitting, it should not be dispensed to the patient.

3. Criteria of a Steep Fitting Lens

   A steep fitting lens may exhibit one or more of the following characteristics: insufficient movement with the blink, conjunctival indentation and resistance when pushing the lens up digitally with the lower lid. If the VISTAKON® (narafilcon B) Contact Lens is judged to be steep fitting, it should not be dispensed to the patient.

If the initial VISTAKON® (narafilcon B) base curve is judged to be flat or steep fitting, the alternate base curve, if available, should be trial fit and evaluated after the patient has adjusted to the lens. The lens should move freely when manipulated digitally with lower lid, and then return to a properly centered position when released. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

II. SPHERICAL LENS FITTING GUIDELINES

A spherical over-refraction should be performed to determine the final lens power after the lens fit is judged acceptable. The spherical over-refraction should be combined with the trial lens power to determine the final lens prescription. The patient should experience good visual acuity with the correct lens power unless there is excessive residual astigmatism.

Example 1:		
Diagnostic lens:		-2.00 D
	Spherical over-refraction	-0.25 D
	Final lens power:	-2.25 D

Example 2:		
Diagnostic lens:		-2.00 D
	Spherical over-refraction	+0.25 D
	Final lens power:	-1.75 D

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow up information in **PATIENT MANAGEMENT**).

III. TORIC FITTING GUIDELINES

Although most aspects of the fitting procedure are identical for all types of soft contact lenses, including torics, there are some additional steps and/or rules to follow to assure the proper fit of toric lenses.

The only new steps you must follow in prescribing the VISTAKON® (narafilcon B) Toric Contact Lenses are that you must determine the stability, repeatability and drift angle of the lens axis so that you can prescribe the correct lens axis for your patient.

A. How to Determine Lens Cylinder and Axis Orientation for VISTAKON® Toric Lenses

1. Locate the Orientation Marks

To help determine the proper orientation of the toric lens, you'll find two primary marks about 1mm from the lens edge representing the vertical position on opposite ends of the lens at 6 and 12 o'clock (Fig. 1). Because of the lens' ballasting system, either mark can represent the vertical position – there is no "top" and "bottom" as in a prism-ballasted lens. You don't need to view both marks to assess orientation; simply look for the 6 o'clock mark as you would with a prism-ballasted lens.

Figure 1

You'll need a biomicroscope and a 1mm or 2mm parallelepiped to highlight the marks when the lens is fitted to the eye. There are a number of techniques you can use to improve the visibility of the 6 o'clock mark. With your parallelepiped and medium magnification (10x or 15x), slowly pan down the lens, looking just below the direct illumination at the retroilluminated area. Backlighting the mark this way should make them more visible. Sometimes manipulating the lower lid may be necessary to uncover the mark.

2. Observe Lens Rotation and Stability

Observe the position and stability of the "bottom" mark. It usually stabilizes at the 6 o'clock position. If it does, calculation of the lens power will be straightforward. The 6 o'clock position is not a "must", however; the absolute requirement is that the axis position be stable and repeatable.

The mark may stabilize somewhat left or right (drift) of the vertical meridian and still enable you to fit a toric lens for that eye, as long as the lens always returns to the same "drift axis" position after settling. The deviation can be compensated for in the final prescription. Your objective is to ensure that whatever position the initial lens assumes near 6 o'clock, this position must be stable and repeatable. With full eye movement or heavy blink, you may see the marks swing away, but they must return quickly to the original stable position. If the lens does not return quickly, you may need to select a different lens.

Assessing Rotation

Imagine the eye as a clock dial and every hour represents a 30° interval. If the orientation mark of the initial lens stabilizes somewhat left or right of the vertical position, the final lens will orient on the eye with the same deviation. You can use an axis reticule in the slit lamp or

use a line-scribed lens in a spectacle trial frame to measure or estimate the "drift angle" of the cylinder axis.

To compensate for this "drift", measure or estimate the "drift", then add or subtract it from the refractive axis to determine the correct cylinder axis. Use the LARS (Left Add, Right Subtract) method to determine which direction to compensate.

B. How to determine the Final Lens Power for VISTAKON® (narafilcon B) Toric Contact Lens

When the diagnostic lens has its axis aligned in the same meridian as the patient's refractive axis, a spherocylindrical over-refraction may be performed and visual acuity determined. However, in the case of crossed axes, such as when the diagnostic lens axis is different from the patient's refractive axis, it is not advisable to over-refract because of the difficulty in computing the resultant power.

In fitting contact lenses, it is customary to prescribe the full power in the sphere. In the cylinder, however, any lens rotation is visually disturbing to the patient, so it's more practical to prescribe as weak a cylinder as possible. So, here is how to determine the final lens power.

For the Sphere:

If sphere alone or combined sphere and cylinder Rx $\geq \pm 4.00$D, compensate for vertex distance. If sphere alone or combined sphere and cylinder Rx $\leq \pm 4.00$D, vertex compensation is not necessary.

For the Cylinder:

Adjust the axis by the drift angle using LARS. Choose a cylinder that is ≤ 0.25D from the refractive cylinder.

Case Examples

Example 1
Manifest (spectacle) refraction:
O.D. –2.50 -1.25 x 180 20/20
O.S. –2.00 -1.00 x 180 20/20

Choose a diagnostic lens for each eye with an axis as close to 180° as possible. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate, based on the patient's initial response to the lens.

Check the orientation of the axis mark. If the bottom axis mark is in the 6 o'clock position on both eyes, choose the appropriate cylinder as listed previously.

Here is the Rx Prescribed/Ordered:
O.D. -2.50 -1.25 x 180
O.S. –2.00 -0.75 x 180

Example 2
Manifest (spectacle) refraction:
O.D. –3.00 -1.00 x 90 20/20
O.S. –4.75 -2.00 x 90 20/20

Choose diagnostic lenses of –3.00 –0.75 x 90 for the right eye and –4.50 -1.75 x 90 for the left eye, the nearest lenses available to the spherical power and axis needed. Place the lens on each eye

and allow a minimum of 3 minutes for it to equilibrate. The orientation mark on the right lens rotates left from the 6 o'clock position by 10°.

The fitting indicates the following:

Right Eye

Compensate the 10° axis drift by adding it to the manifest refraction axis. Here is the Rx prescribed:
O.D. –3.00 –0.75 x 100

Left Eye

The lens on the left eye shows good centration, movement and a consistent tendency for the mark to drift right by 10° from the 6 o'clock position following a forced blink.

Since the manifest refraction called for a power of –4.75D, adjust for the vertex distance and reduce the sphere by 0.25D and prescribe the –1.75D cylinder. Compensate for the 10° axis drift by subtracting it from the manifest refraction. Here is the Rx prescribed:
O.S. –4.50 –1.75 x 80

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow up information in **PATIENT MANAGEMENT**).

IV. MULTIFOCAL FITTING GUIDELINES

A. Presbyopic Needs Assessment & Patient Education

Multifocal contact lenses may produce compromise to vision under certain circumstances and the patient should understand that they might not find their vision acceptable in specific situations (i.e., reading a menu in a dim restaurant, driving at night in rainy/foggy conditions, etc.). Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments. Occupational and environmental visual demands should be considered. If the patient requires critical visual acuity and stereopsis, it should be determined by trial whether this patient can function adequately with the VISTAKON® (narafilcon B) Multifocal Contact Lens. VISTAKON® (narafilcon B) Multifocal Contact Lens wear may not be optimal for such activities as:

1. visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
2. driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with the VISTAKON® (narafilcon B) Multifocal Contact Lens should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

VISTAKON® (narafilcon B) Multifocal Contact Lenses are not recommended for patients who have –1.00 D or greater of refractive cylinder as this level of uncorrected cylinder may lead to additional visual compromise.

VISTAKON® (narafilcon B) Multifocal Contact Lenses come in the following ADD powers:
Lens "LOW" ="low" near ADD lens
Lens "MID" = "medium" near ADD lens
Lens "HIGH" = "high" near ADD lens

VISTAKON® (narafilcon B) Multifocal Contact Lenses Fitting Instructions

Step 1	Determine: - Eye dominance (the methods described in MONOVISION SPHERE AND TORIC FITTING GUIDELINES may be used) - Spherical equivalent distance prescription (vertex corrected if necessary and rounded to less minus if between powers) - Near ADD
Step 2	Select the initial trial lens as follows: - For each eye select the trial lens distance power that is closest to the patient's distance spherical equivalent. Select the near power of the lens based on the patients ADD range as follows: ADD: +0.75 to +1.25 use a "LOW" near ADD lens on each eye ADD: +1.50 to +1.75 use a "MID" near ADD lens on each eye ADD: +2.00 to+2.50 use a "HIGH" near ADD lens on each eye
Step 3	Allow the lens to settle for a minimum 10 minutes.
Step 4	- Assess distance and near vision binocularly and monocularly. - Demonstrate the vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate and near. - Make adjustments in power as necessary (see **Multifocal Troubleshooting** below). The use of hand-held trial lenses is recommended. - If distance and near vision are acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow up information in PATIENT MANAGEMENT).

C. Multifocal Troubleshooting

Unacceptable Near Vision:

Determine the amount of additional plus, or less minus, over one or both eyes that is acceptable while checking the effect on distance and near vision. If vision is still not acceptable change the non-dominant eye to the next highest ADD power.

Unacceptable Distance Vision:

Determine the amount of additional minus, or less plus, over one or both eyes that is acceptable while checking the effect on distance and near vision. If vision is still not acceptable change the dominant eye to the next lowest ADD power. If the patient is wearing two low ADD lenses change the dominant eye to a sphere lens with a power equal to the spherical equivalent distance prescription.

Unacceptable Distance and Near Vision:

Determine the amount of additional plus and/or minus over one or both eyes that is acceptable while checking the effect on distance and near vision. If additional plus and/or minus is not required change the lens power in the dominant eye to the next lowest ADD power and the lens power in the non-dominant eye to the next highest ADD power if applicable.

V. MULTIFOCAL-TORIC FITTING GUIDELINES

A. Presbyopic Needs Assessment & Patient Education

Multifocal contact lenses may produce compromise to vision under certain circumstances and the patient should understand that they might not find their vision acceptable in specific situations (i.e., reading a menu in a dim restaurant, driving at night in rainy/foggy conditions, etc.). Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments. Occupational and environmental visual demands should be considered. If the patient requires critical visual acuity and stereopsis, it should be determined by trial whether this patient can function adequately with the VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens. VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens wear may not be optimal for such activities as:

1. visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
2. driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with the VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

B. VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens Parameter Selection (Trial lens fitting)

A trial fitting is performed in the office to allow the patient to experience presbyopic correction with the VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens and to determine the proper lens fit of the contact lenses (see Criteria of A Properly Fit Lens in the General Fitting Instructions). Since lens centration is important for multifocal toric lens performance, insert the trial lens with the steepest sagittal depth available.

C. VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens Selection

In is important when prescribing the VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens that you determine the stability, repeatability and drift angle of the lens axis so that you can prescribe the correct lens axis for your patient.

Initial Lens Power Selection

a) VISTAKON® (narafilcon B) Multifocal-Toric Contact Lenses come in the following ADD powers:

Lens "LOW" ="low" near ADD lens
Lens "MID" = "medium" near ADD lens
Lens "HIGH" = "high" near ADD lens

2. The cylinder power selected should be equal to the vertex adjusted cylinder power of the best corrected spectacle Rx.

Note: Any lens rotation is visually disturbing to the patient, so it's more practical to prescribe as weak a cylinder power as possible. A great deal of experience with patients has shown that it is possible to under-prescribe the minus cylinders near 180 ° ("with the rule") by as much as 30% and to under-prescribe minus cylinders near 90 ° ("against the rule") by as much as 20%. Therefore, if the cylinder correction is between two available cylinder powers, choose the less minus power.

Step 1	Determine: - Eye dominance (the methods described in MONOVISION SPHERE AND TORIC FITTING GUIDELINES may be used) - Spherical equivalent distance prescription (vertex corrected if necessary and rounded to less minus if between powers) - Near ADD
Step 2	Select the initial trial lens as follows: Initial Distance Power Selection For each eye, select the trial lens distance power that is closest to the patient's distance spherical equivalent. A patient with a spectacle Rx: (O.D.) = -3.00D –1.50D x 180, +1.50D ADD (O.S.) = -2.25D –1.50D x 170, +1.50D ADD Initial VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens distance power selection: (O.D.) = -3.00D –1.25D x 180 (O.S.) = -2.50D –1.25D x 170 Note: 1. Since the spectacle cylinder power is between two available VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens cylinder powers, choose the less minus contact lens cylinder power. Therefore, the initial VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens cylinder power selection = +1.25D 2. Choose the diagnostic lens with an axis closest to the patient's spectacle cylinder axis. Select the near power of the lens based on the patient's ADD range as follows: ADD: +0.75 to +1.25 use a "LOW" near ADD lens on each eye ADD: +1.50 to +1.75 use a "MID" near ADD lens on each eye ADD: +2.00 to+2.50 use a "HIGH" near ADD lens on each eye
Step 3	Allow the lens to settle for a minimum 10 minutes.
Step 4	- Assess distance and near vision binocularly and monocularly. - Demonstrate the vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate and near. - Make adjustments in power as necessary (see **Multifocal-Toric Troubleshooting** below). The use of hand-held trial lenses is recommended.

Step 5	**A. Locate the Orientation Marks** To help determine the proper orientation of the toric lens, you'll find two primary marks about 1mm from the lens edge representing the vertical position on opposite ends of the lens at 6 and 12 o'clock (Fig. 1). Because of the lens' ballasting system, either mark can represent the vertical position – there is no "top" and "bottom" as in a prism-ballasted lens. You don't need to view both marks to assess orientation; simply look for the 6 o'clock mark as you would with a prism-ballasted lens. Figure 1 You'll need a biomicroscope and a 1mm or 2mm parallelepiped to highlight the marks when the lens is fitted to the eye. There are a number of techniques you can use to improve the visibility of the 6 o'clock mark. With your parallelepiped and medium magnification (10x or 15x), slowly pan down the lens, looking just below the direct illumination at the retroilluminated area. Backlighting the mark this way should make them more visible. Sometimes manipulating the lower lid may be necessary to uncover the mark. **B. Observe Lens Rotation and Stability** Observe the position and stability of the "bottom" mark. It usually stabilizes at the 6 o'clock position. If it does, calculation of the lens power will be straightforward. The 6 o'clock position is not a "must", however; the absolute requirement is that the axis position be stable and repeatable. The mark may stabilize somewhat left or right (drift) of the vertical meridian and still enable you to fit a toric lens for that eye, as long as the lens always returns to the same "drift axis" position after settling. The deviation can be compensated for in the final prescription. Your objective is to ensure that whatever position the initial lens assumes near 6 o'clock, this position must be stable and repeatable. With full eye movement or heavy blink, you may see the marks swing away, but they must return quickly to the original stable position. If the lens does not return quickly, you may need to select a different lens. **Assessing Rotation** Imagine the eye as a clock dial and every hour represents a 30° interval. If the orientation mark of the initial lens stabilizes somewhat left or right of the vertical position, the final lens will orient on the eye with the same deviation. You can use an axis reticule in the slit lamp or use a line-scribed lens in a spectacle trial frame to measure or estimate the "drift angle" of the cylinder axis. To compensate for this "drift", measure or estimate the "drift" and round it off into 5° increments, then add or subtract it from the refractive axis to determine the correct cylinder axis. Use the LARS (Left Add, Right Subtract) method to determine which direction to compensate. **C. Final Lens Determination** When the diagnostic lens has its axis aligned in the same meridian as the patient's refractive axis, a spherocylindrical over-refraction may be performed and visual acuity determined. However, in the case of crossed axes, such as when the diagnostic lens axis is different from the spectacle cylinder axis, it is not advisable

Step 5 (cont.)

In fitting contact lenses, it is customary to prescribe the full power in the sphere. In the cylinder, however, any lens rotation is visually disturbing to the patient, so it's more practical to prescribe as weak a cylinder as possible. So, here is how to determine the final lens power.

For the Sphere:

If sphere alone or combined sphere and cylinder Rx >±4.00D, compensate for vertex distance. If sphere alone or combined sphere and cylinder Rx ≤ ±4.00D, vertex compensation is not necessary.

For the Cylinder:

Adjust the axis by the drift angle using LARS. Choose a cylinder that is ≤ 0.50D from the refractive cylinder.

Case Examples

Example 1
Manifest (spectacle) refraction:
O.D. –2.50 -1.25 x 180 20/20
O.S. –2.00 -1.00 x 180 20/20

Choose a diagnostic lens for each eye with an axis as close to 180° as possible. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate, based on the patient's initial response to the lens.

Check the orientation of the axis mark. If the bottom axis mark is in the 6 o'clock position on both eyes, choose the appropriate cylinder as listed previously.

Here is the Rx Prescribed/Ordered:
O.D. -2.50 -1.25 x 180
O.S. –2.00 -0.75 x 180

Example 2
Manifest (spectacle) refraction:
O.D. –3.00 -1.00 x 90 20/20
O.S. –4.75 -2.00 x 90 20/20

Choose diagnostic lenses of –3.00 –0.75 x 90 for the right eye and –4.50 -1.75 x 90 for the left eye, the nearest lenses available to the spherical power and axis needed. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate. The orientation mark on the right lens rotates left from the 6 o'clock position by 10°.

The fitting indicates the following:

Right Eye

Compensate the 10° axis drift by adding it to the manifest refraction axis. Here is the Rx prescribed:
O.D. –3.00 –0.75 x 100

	Left Eye The lens on the left eye shows good centration, movement and a consistent tendency for the mark to drift right by 10° from the 6 o'clock position following a forced blink. Since the manifest refraction called for a power of –4.75D, adjust for the vertex distance and reduce the sphere by 0.25D and prescribe the –1.75D cylinder. Compensate for the 10° axis drift by subtracting it from the manifest refraction. Here is the Rx prescribed: O.S. –4.50 –1.75 x 80 C. If no adjustment was required and lens fit (see Criteria of A Properly Fit Lens in General Fitting Guidelines), axis orientation and rotational stability are acceptable, and the patient obtains acceptable visual performance, the trial lenses should be dispensed for up to one week of wear (see dispensing and follow up information in **PATIENT MANAGEMENT**). D. If the patient does not obtain acceptable visual performance, please see the **Multifocal-Toric Troubleshooting** section.

D. Multifocal-Toric Troubleshooting:

Ensure that the lenses have been inserted properly. Some patients will exhibit poor vision from a lens that is inside out, but still report good comfort and the lens will exhibit good fit characteristics. If a lens is inside out, remove the lens and insert it properly. Allow the patient to adapt to the lens again before evaluating vision.

If lenses were inserted properly, ensure that axis orientation and rotational stability is acceptable. If the axis is not located at the 6 o'clock position, adjust the axis as previously mentioned in Step 5. If the axis is oriented properly and the rotational stability is acceptable but the patient has unacceptable vision, conduct a distance over-refraction to ensure the patient has the least minus/most plus distance correction (i.e., ensure that the patient is not over-minused at distance). If the patient does not have the least minus/most plus distance correction, adjust the prescription and reassess the visual performance.

If the patient does have the least minus/most plus distance correction (i.e., is not over-minused at distance) but has unacceptable visual performance, please follow the suggestions below.

Unacceptable Near Vision:

Determine the amount of additional plus, or less minus, over one or both eyes that is acceptable while checking the effect on distance and near vision. If vision is still not acceptable change the non-dominant eye to the next highest ADD power.

Unacceptable Distance Vision:

Determine the amount of additional minus, or less plus, over one or both eyes that is acceptable while checking the effect on distance and near vision. If vision is still not acceptable change the dominant eye to the next lowest ADD power. If the patient is wearing two low ADD lenses change the dominant eye to a sphere lens with a power equal to the spherical equivalent distance prescription.

Unacceptable Distance and Near Vision:

Determine the amount of additional plus and/or minus over one or both eyes that is acceptable while checking the effect on distance and near vision. If additional plus and/or minus is not required change the lens power in the dominant eye to the next lowest ADD power and the lens power in the non-dominant eye to the next highest ADD power if applicable.

Prior to dispensing the lenses, check vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate and near. If distance and near vision are acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses, instructing the patient to return in one week for reassessment.

VI. MONOVISION (SPHERICAL AND TORIC FITTING GUIDELINES)

A. Patient Selection

Monovision Needs Assessment

For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than 1.00 D) in one eye may not be a good candidate for monovision correction with the VISTAKON® (narafilcon B) Contact Lens.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis), it should be determined by trial whether this patient can function adequately with monovision correction. Monovision contact lens wear may not be optimal for such activities as:

(a) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and

(b) driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with spectacles (multifocal, bifocal, trifocal, readers, progressives). Each patient should understand that Monovision, as well as other presbyopic alternatives, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments (e.g., reading a menu in a dim restaurant, driving at night in rainy/foggy conditions, etc.). During the fitting process, it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision and straight ahead and upward gaze that monovision contact lenses provide.

B. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following two methods for eye dominance can be used.

1. Ocular Preference Determination Methods

Method 1: Determine which eye is the "sighting eye". Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2: Determine which eye will accept the added power with the least reduction in vision. Place a hand-held trial lens equal to the spectacle near ADD in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near ADD lens over the right or left eye.

Other methods include the refractive error method and the visual demands method.

2. Refractive Error Method

For anisometropic correction, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

3. Visual Demands Method

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction, correct the eye on that side for near.

Example:
A secretary who places copy to the left side of the desk will function best with the near lens on the left eye.

C. Special Fitting Characteristics

1. Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may only require a distance lens.

Example:
A presbyopic emmetropic patient who requires a +1.75D ADD would have a +1.75D lens on the near eye and the other eye left without a lens.

A presbyopic patient requiring a +1.50D ADD who is –2.50D myopic in the right eye and –1.50D myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

2. Near ADD Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

3. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the General Fitting Instructions for base curve selection in this Package Insert.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine the distance correction and the near correction. Next determine the near ADD. With trial lenses of the proper power in place, observe the reaction to this mode of correction.

Allow the lenses to settle for about 20 minutes with the correct power lenses in place. Walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tests are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g., typewritten copy) at first and then graduate to newsprint and finally smaller type sizes.

After the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

4. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process, the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

Other Suggestions

The success of the monovision technique may be further improved by having your patient follow the suggestions below:

- Have a third contact lens (distance power) to use when critical distance viewing is needed.
- Have a third contact lens (near power) to use when critical near viewing is needed.

- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Monovision fitting can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of clear near vision and straight ahead and upward gaze with monovision.

The decision to fit a patient with a monovision correction is most appropriately left to the eye care professional in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the "VISTAKON® (narafilcon B) Patient Instruction Guide".

PATIENT MANAGEMENT

Dispensing Visit

- **PROVIDE THE PATIENT WITH A COPY OF THE APPROPRIATE VISTAKON® PATIENT INSTRUCTION GUIDE. REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING SCHEDULE.**
- Schedule a follow-up examination.

Follow-up Examinations

- Follow-up care (necessary to ensure continued successful contact lens wear) should include routine periodic progress examinations, management of specific problems, if any, and a review with the patient of the wear schedule and handling procedures.

- Recommended Follow-up Examination Schedule for VISTAKON® Contact Lenses (complications and specific problems should be managed on an individual patient basis):

1. One week from the initial lens dispensing to patient
2. One month post-dispensing
3. Every three to six months thereafter

Preferably, at the follow-up visits, lenses should be worn for at least six hours.

- Recommended Procedures for Follow-Up Visits:

1. Solicit and record patient's symptoms, if any.

2. Measure visual acuity monocularly and binocularly at distance and near with the contact lenses.

3. Perform an over-refraction at distance and near to check for residual refractive error.

4. With the biomicroscope, judge the lens fitting characteristics (as described in the General Fitting Guidelines) and evaluate the lens surface for deposits and damage.

5. Following lens removal, examine the cornea and conjunctiva with the biomicroscope and fluorescein (unless contraindicated).
   - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
   - The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear and/or a poorly fitting lens.
   - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.
6. Periodically perform keratometry and spectacle refractions. The values should be recorded and compared to the baseline measurements.

If any observations are abnormal, use professional judgment to alleviate the problem and restore the eye to optimal conditions. If the criteria for successful fit are not satisfied during any follow-up examinations, repeat the patient's trial fitting procedure and refit the patient.

WEARING SCHEDULE

The wearing schedule should be determined by the Eye Care Professional. Patients tend to over wear the lenses initially. The Eye Care Professional should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the Eye Care Professional, are also extremely important.

DAILY DISPOSABLE WEAR (less than 24 hours, while awake)

- For daily disposable wear, VISTAKON® recommends that the VISTAKON® (narafilcon B) Contact Lenses be discarded upon removal.

The maximum suggested wearing time for these lenses is:

Day	Hours
1	6-8
2	8-10
3	10-12
4	12-14
5 and after	all waking hours

LENS CARE DIRECTIONS

When lenses are dispensed, the Eye Care Professional should provide the patient with appropriate and adequate warnings and instructions in accordance with the individual patient's lens type and wearing schedule.

For VISTAKON® (narafilcon B) Contact Lenses prescribed for daily wear single use only: The Eye Care Professional should review with patients that no cleaning or disinfection is needed. Patients should always dispose of lenses when they are removed and have replacement lenses or spectacles available.

CARE FOR A STICKING (NON-MOVING) LENS

If the lens sticks (stops moving), the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after a few minutes, the patient should immediately consult the Eye Care Professional.

EMERGENCIES
The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED
Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with methyl ether cellulose. The plastic package is marked with base curve, diopter power, diameter, color (visibility tint noted on visibility tinted product only), lot number and expiration date. [ADD power, cylinder and axis will be included as appropriate].

REPORTING OF ADVERSE REACTIONS
All serious adverse experiences and adverse reactions observed in patients wearing VISTAKON® Contact Lenses or experienced with the lenses should be reported to:

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, FL 32256
Tel: 1-800-843-2020
www.acuvue.com

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AT 11 09 00
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Revision Number: Version 1.0

PATIENT INSTRUCTION GUIDE
FOR SINGLE USE DAILY WEAR ONLY

VISTAKON® (narafilcon B) Contact Lenses (Spherical)
VISTAKON® (narafilcon B) Contact Lenses (Multifocal)
VISTAKON® (narafilcon B) Contact Lenses (Toric)
VISTAKON® (narafilcon B) Contact Lenses (Multifocal-Toric)

Visibility Tinted with UV Blocker

From the makers of ACUVUE® Brand Contact Lenses

TABLE OF CONTENTS

INTRODUCTION
INDICATIONS (USES) WEARING RESTRICTIONS
CONTRAINDICATIONS (REASONS NOT TO USE)
WARNINGS
PRECAUTIONS
ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)
PERSONAL CLEANLINESS FOR LENS HANDLING AND INSERTION
- Preparing the Lens for Wearing
- Opening the Multipack and Lens Package
- Handling the Lenses
- Placing the Lens on the Eye
- Centering the Lens
- Removing the Lens
- CARING FOR YOUR LENSES
- Basic Instructions
- Care for Sticking (Non-Moving) Lens
- Lens Case Cleaning and Maintenance
- Care for a Dried Out (Dehydrated) Lens
- Emergencies

INSTRUCTIONS FOR THE PRESBYOPIC PATIENT (MONOVISION & MULTIFOCAL)
WEARING AND APPOINTMENT SCHEDULES
PATIENT/EYE CARE PROFESSIONAL INFORMATION
GLOSSARY OF TECHNICAL TERMS
SYMBOLS KEY

CAUTION: Federal U.S.A law restricts this device to sale by or on the order of a licensed practitioner.

INTRODUCTION

The information and instructions contained in this booklet apply only to the VISTAKON® (narafilcon B) Contact Lenses. Your contact lenses are intended to be used for daily wear single use only within the VISTAKON® planned lens replacement system.

Please refer to the Glossary of Technical Terms for definitions of medical/technical terminology used in this booklet. In addition, the Symbols Key provides an explanation of symbols that may appear on the lens packaging. After the wearing period prescribed by your Eye Care Professional, your contact lenses should be discarded and replaced with a new sterile pair. If you have any questions, always ask your Eye Care Professional. By replacing your contact lenses on a daily basis, lens deposits, which can affect vision and cause irritation and discomfort to the eye, have little chance to build up over time as with conventional lens wear. When you discard the lens, you dispose of potential deposit build-up problems. Your contact lenses are visibility tinted with a UV Blocker. An ultraviolet (UV) radiation absorbing ingredient is used to block UV radiation.

For your eye health, it is important that your contact lenses be worn only as prescribed by your Eye Care Professional. Your Eye Care Professional should be kept fully aware of your medical history. Your Eye Care Professional will tailor a total program of care based on your specific needs. He or she will review with you all instructions for lens handling and care, including how to safely and easily open the packaging. You will also be instructed on how to properly insert and remove lenses. This booklet will reinforce those instructions.

If you have any questions, always ask your Eye Care Professional.

INDICATIONS (USES) AND WEARING RESTRICTIONS

All VISTAKON® (narafilcon B) Soft Contact Lenses with UV Blocker help protect against transmission of harmful UV radiation to the cornea and into the eye.

The VISTAKON® (narafilcon B) Soft Contact Lens (spherical) is indicated 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® (narafilcon B) Multifocal Soft Contact Lens is indicated 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® (narafilcon B) Toric Soft Contact Lens is indicated 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® (narafilcon B) Multifocal-Toric Soft Contact Lens is indicated 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.

Your Eye Care Professional should prescribe the lenses for daily wear single use only. The Eye Care Professional will determine your wearing schedule. Your lenses are to be discarded upon removal. Therefore, no cleaning or disinfecting is required.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the VISTAKON (narafilcon B) Contact Lens when any of the following conditions exist:
- Inflammation or infection in or around the eye or eyelids
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
- Any previously diagnosed condition that makes contact lens wear uncomfortable.
- Severe dry eye
- Reduced corneal sensitivity (corneal hypoesthesia)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or surrounding tissues (adnexa) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated

WARNINGS

What you should know about Contact Lens Wear

- Problems with contact lenses or lens care products could result in serious injury to the eye. Proper use and care of your contact lenses and lens care products, including lens cases, are essential for the safe use of these products.
- Eye problems, including a sore or lesion on the cornea (corneal ulcers) can develop rapidly and lead to loss of vision.
- The risk of an infected sore or lesion on the cornea (ulcerative keratitis) greater for people who wear extended wear contact lenses than for those who wear daily wear lenses.
- When daily wear users wear their lenses overnight (outside the approved use), the risk of infected sore or lesion on the cornea (ulcerative keratitis) is greater than among those who do not wear them while sleeping.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.
- The risk of ulcerative keratitis among contact lens users who smoke is greater than among non-smokers.
- If you experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, you should immediately remove your lenses and promptly contact your Eye Care Professional. It is recommended that you see your Eye Care Professional routinely as directed.

*__WARNING__: **UV absorbing contact lenses are not substitutes for protective UV absorbing eyewear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.**

Note: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your Eye Care Professional for more information.

PRECAUTIONS

Handling Precautions:

• **DO NOT** use if the sterile blister package is opened or damaged.
• Before leaving the Eye Care Professional's office, you should be able to promptly remove the lenses or should have someone else available who can remove the lenses for you.
• **Always wash and rinse your hands before handling lenses**. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in your eyes or on your lenses. It is best to put on your lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
• **DO NOT** touch your contact lenses with your fingers or hands if they are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to your eye.
• **Carefully** follow the handling, insertion, removal and wearing instructions in this booklet and those prescribed by the Eye Care Professional.
• **Always** handle lenses carefully and avoid dropping them.
• **Never** use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour the lens and the packing solution into the hand.
• **Do not** touch the lens with your fingernails.

Lens Wearing Precautions:

• You should remove your lenses immediately if your eyes become red or irritated.
• **Never** wear your lenses beyond the period recommended by your Eye Care Professional.
• If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and **keep your eyes closed** until the spray has settled.
• **Avoid** all harmful or irritating vapors and fumes while wearing lenses.
• **Ask** your Eye Care Professional about wearing contact lenses during sporting activities, especially swimming and other water sports. Exposing contact lenses to water during swimming or while in a hot tub **may increase the risk of eye infection** from microorganisms.
• **Always throw away** lenses worn as prescribed by your Eye Care Professional.

Lens Care Precautions:

• The Eye Care Professionals should review with patients that no cleaning or disinfecting is needed with daily single use lenses. Patients should always dispose of lenses when they are removed and have replacement lenses or spectacles available.

Other Topics to discuss with Your Eye Care Professional:

• If you wear your contact lenses to correct presbyopia using monovision or if your contact lenses are Multifocal or Multifocal-Toric to correct presbyopia you **may not** achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered by our eye care professional in conjunction with you when selecting the most appropriate type of lens for you.

• **Always** contact your Eye Care Professional before using any medicine in your eyes.
• **Be aware** that certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers and those for motion sickness may cause dryness of the eye, increased lens awareness or blurred vision. Always inform your eye care professional if you experience any problems with your lenses while taking such medications. Depending on the severity, your eye care professional may prescribe the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.
• **Be aware** that if you use oral contraceptives, you could develop visual changes or changes in lens tolerance when using contact lenses.
• As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes.

Who should know that you are wearing Contact Lenses:

• **Inform** your doctor (Health Care Professional) about being a contact lens wearer.
• **Always** inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.

ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)

Be aware that the following problems may occur when wearing contact lenses:

• Your eyes may burn, sting and/or itch.
• There may be less comfort than when the lens was first placed on your eye.
• There may be a feeling of something in your eye (foreign body, scratched area).
• There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers and corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.
• There may be excessive watering, unusual eye secretions or redness of your eye.
• Poor visual acuity, blurred vision, rainbows or halos around objects, sensitivity to light (photophobia) or dry eyes may also occur if your lenses are worn continuously or for too long a time.

You should conduct a simple 3-part self-examination at least once a day.

Ask yourself:
- How do the lenses feel on my eyes?
- How do my eyes look?
- Do I continue to see well?

If you report any problems, you should IMMEDIATELY REMOVE YOUR LENS.

If the discomfort or problem stops, you should look closely at the lens.

If the lens is in any way damaged, you SHOULD NOT put the lens back on your eye. You should discard the lens and insert a new fresh lens on your eye.

If your lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, you should dispose of the lens and insert a new fresh lens.

If the problem continues, you SHOULD NOT put the lens back on your eye but IMMEDIATELY CONSULT YOUR EYE CARE PROFESSIONAL.

When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. **Seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

PERSONAL CLEANLINESS FOR LENS HANDLING AND INSERTION

1. Prepare the Lens for Wearing

It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:

- Always wash your hands thoroughly with a mild soap, rinse completely and dry with a lint free towel before touching your lenses.
- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips, and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.

Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

2. Opening the Multipack and Lens Package

Multipack

Each multipack contains individually packaged lenses. Each lens comes in its own lens package designed specifically to maintain sterility. You may choose to keep your lenses inside the multipack for storage until you are ready to use them.

Lens Package

To open an individual lens package, follow these simple steps:

1. Shake the lens package and check to see that the lens is floating in the solution.

2. Peel back the foil closure to reveal the lens. By stabilizing the lens package on the table-top, you will minimize the possibility of a sudden splash.

Occasionally, a lens may adhere to the inside surface of the foil when opened, or to the plastic package itself. This will not affect the sterility of the lens. It is still perfectly safe to use. Carefully remove and inspect the lens following the handling instructions.

3. Handling the Lenses

• When you first get your lenses, be sure that you are able to put the lenses on and remove them before leaving your Eye Care Professional's office.
• Develop the habit of always working with the same lens first to avoid mix-ups.
• Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or tears. If the lens appears damaged, do not use it. Use the next lens in the multipack.

4. Placing the Lens on the Eye

Remember, always start with the same eye.

Once you have opened the lens package, removed, and examined the lens, follow these steps to apply the lens to your eye:

1. BE SURE THE LENS IS NOT INSIDE-OUT by following either of the following procedures:
   • Place the lens on the tip of your index finger and check its profile. The lens should assume a natural, curved, bowl-like shape. If the lens edges tend to point outward, the lens is inside out. Another method is to gently squeeze the lens between the thumb and forefinger. The edges should turn inward. If the lens is inside out, the edges will turn slightly outward.

OR

   • Place the lens on the tip of your index finger and, looking up at the lens, locate the numbers 123. 1-2-3 indicates correct orientation while a reverse of 1-2-3 indicates the lens is inside out. If the lens is inside out (reverse 1-2-3), invert the lens and locate the numbers again to confirm correct lens orientation.

2. Place the middle finger of the same hand close to your lower eyelashes and pull down the lower lid.

3. Use the index finger or middle finger of the other hand to lift the upper lid.

4. Place the lens on the eye.

5. Gently release the lids and blink. The lens will center automatically

6. Use the same technique when inserting the lens for your left eye

There are other methods of lens placement. If the above method is difficult for you, your Eye Care Professional will provide you with an alternate method.

After you have successfully inserted your lenses, you should ask yourself:
- Do I see well?
- How do the lenses feel on my eyes?
- How do my eyes look?

Note: If after placement of the lens, your vision is blurred, check for the following:

- The lens is not centered on the eye (see "Centering the Lens", next in this booklet).
- If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:

    a. Cosmetics or oils on the lens. Dispose of the lens and insert a new fresh lens.
    b. The lens is on the wrong eye.
    c. The lens is inside out (it would also not be as comfortable as normal).

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your Eye Care Professional.

If a lens becomes less comfortable than when it was first inserted or if it is markedly uncomfortable upon insertion, remove the lens immediately and contact your Eye Care Professional.

If your examination shows any problems, IMMEDIATELY REMOVE YOUR LENSES AND CONTACT YOUR EYE CARE PROFESSIONAL.

5. Centering the Lens

A lens, which is on the cornea, will very rarely be displaced onto the white part of the eye during wear. This, however, can occur if insertion and removal procedures are not performed properly. To center a lens, follow either of these procedures:

a. Close your eyelids and gently massage the lens into place through the closed lids.

OR

b. Gently manipulate the off-centered lens onto the cornea while the eye is opened using finger pressure on the edge of the upper lid or lower lid.

6. Removing the Lens

Always remove the same lens first.

a. Wash, rinse and dry your hands thoroughly.

CAUTION: Always be sure the lens is on the cornea before attempting to remove it. Determine this by covering the other eye. If vision is blurred, the lens is either on the white part of the eye or it is not on the eye at all. To locate the lens, inspect the upper area of the eye by looking down into a mirror while pulling the upper lid up. Then inspect the lower area by pulling the lower lid down.

b. There are two recommended methods of lens removal: the Pinch Method and the Forefinger and Thumb Method. You should follow the method that is recommended by your Eye Care Professional.

Pinch Method:

1. Look up, slide the lens to the lower part of the eye using the forefinger.

2. Gently pinch the lens between the thumb and forefinger.

3. Remove the lens.

Forefinger and Thumb Method:

1. Place your hand or towel under your eye to catch the lens.

2. Place your forefinger on the center of the upper lid and your thumb on the center of the lower lid.

3. Press in and force a blink. The lens should fall onto your hand or the towel.

Once the lens is removed, simply follow the lens care directions recommended by your Eye Care Professional.

> **Note:** The lens may come out, but remain on the eyelid, finger or thumb.

4. Remove the other lens by following the same procedure.

5. Follow the required lens care procedures described under the heading, "Caring For Your Lenses (Cleaning, Rinsing, Disinfecting, Storage and Rewetting/Lubricating)".

> **Note**: If these methods of removing your lens are difficult for you, your Eye Care Professional will provide you with an alternate method.

CARING FOR YOUR LENSES

1. Basic Lens Care Instructions

If you require only vision correction, but will not or cannot always use the recommended care routine for your lenses, or are unable to put on and remove lenses or have someone available to place and remove them, you should not try to get and wear contact lenses.

- When you first get your lenses, be sure to put the lenses on and remove them while you are in your Eye Care Professional's office.
- Always wash, rinse, and dry your hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.
- Never rinse your lenses in water from the tap. There are two reasons for this:
  a. Tap water may contain impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
  b. You might lose your lens down the drain.

For Single Use Daily Wear:

Remember, there is no cleaning or disinfection needed with VISTAKON® (narafilcon B) Contact Lenses prescribed for daily single use wear only. Always dispose of lenses when they are removed and have replacement lenses or spectacles available.

2. Care For A Sticking (Non-moving) Lens

If a lens sticks (stops moving) on your eye, apply a few drops of the recommended lubricating solution. You should wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues, you should immediately consult your Eye Care Professional.

3. Lens Case Cleaning and Maintenance

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer and allowed to air dry. Lens cases should be replaced at regular intervals, as recommended by the lens case manufacturer or your Eye Care Professional.

4. Care For A Dried Out (Dehydrated) Lens

If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle. If this happens, dispose of the lens and use a new fresh one.

5. Emergencies

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

INSTRUCTIONS FOR THE PRESBYOPIC PATIENT (MONOVISION & MULTIFOCAL)

• You should be aware that, as with any type of lens correction, there are advantages and compromises to presbyopic contact lens correction. The benefit of clear near vision in straight ahead and upward gaze that is available with your contact lenses for monovision and multifocal correction may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to this. Symptoms, such as mild blurred vision and variable vision, may last for a brief period or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your chances for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations that are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first days of wearing your lens. It is recommended that you only drive with Monovision correction if you pass your state drivers license requirements with Monovision correction.

• Some presbyopic patients require supplemental spectacles to wear over your contact lenses for monovision or multifocal correction to provide the clearest vision for critical tasks. You should discuss this with your Eye Care Professional.

• Some presbyopic patients will never be fully comfortable functioning under low levels of lighting, such as driving at night. If this happens, you may want to discuss with your Eye Care Professional having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.

For monovision patients, if you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required. It is important that you follow your Eye Care Professional's suggestions for adaptation to presbyopic contact lens correction. You should discuss any concerns that you may have during and after the adaptation period

.

• The decision to be fit with Monovision or multifocal correction is most appropriately left to the Eye Care Professional, in conjunction with you, after carefully considering and discussing your needs.

WEARING AND APPOINTMENT SCHEDULE

Prescribed Wearing Schedule

Day	Wearing Time (Hours)
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	

Appointment Schedule
Your appointments are on:
Minimum number of hours lenses to be worn at time of appointment:
Month: Year:
Time: Day:

PATIENT/EYE CARE PROFESSIONAL INFORMATION

Next Appointment:
Date:
Dr:
Address:
Phone:

Day Date Hours Worn	Day Date Hours Worn
1	1
2	2
3	3
4	4
5	5
6	6
7	7

IMPORTANT: In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYE CARE PROFESSIONAL IMMEDIATELY.

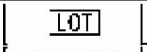
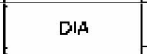
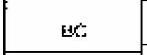
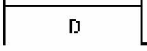
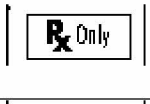
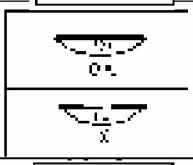
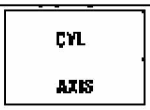
NOTES

Glossary of Technical Terms

Term	Definition
Adnexa	Tissues surrounding the eyeball
Ametropia	Abnormal vision requiring correction for proper focus
Anterior chamber	Internal portion of the eye, between the cornea and iris
Aphakic	An eye that does not have its natural lens (example: after cataract surgery)
Aspherical contact lens	A lens with a curve that is not round, but has different shapes across its surface
Astigmatism	A condition where the cornea is not equally curved in all parts of its surface. It is somewhat oval in shape, causing the visual image to be out of focus (blurred).
Conjunctiva	Membrane that lines the eyelids and the white part of the eye
Conjunctivitis	Inflammation of the conjunctiva
Cornea	Clear front part of the eye that covers the iris, pupil and anterior chamber
Corneal erosion	Wearing away of the surface of the cornea
Corneal staining	When a dye is put onto the eye and shows problems with the corneal surface
Corneal ulcer	A sore or lesion on the cornea
Disinfection	A process that kills harmful microorganisms (germs) which can cause serious eye infections
Edema	Swelling of tissue from excess fluid accumulation
Hydrophilic material	"Water loving" or water absorbing substance
Hyperopia	Farsightedness
Infiltrate	Redness
Iritis	Inflammation of the colored part of the eye (iris)
Inflammation	Swelling, redness, and pain
Monovision	A correction method for presbyopia (loss of reading vision) using contact lenses; one eye is fitted for distance, the other for near vision
Multifocal contact lens	A lens that can correct for both distance and near vision
Myopia	Nearsightedness
Neovascularization	Blood vessels growing into the cornea
Phakic	An eye that possesses its natural lens
Presbyopia	Condition in which as the lenses in the eyes lose some of their elasticity, as occurs with aging, they lose some of their ability to change focus for different distances. Usually becomes significant after age 45.
Spherical contact lens	A lens with a continuously rounded curve
Tarsal abnormalities	Problems with the eyelids
Toric contact lens	A lens with two different optical powers at right angles to each other for the correction of astigmatism`
Toric-Multifocal contact lens	A lens that can correct for both distance and near vision with two different optical powers at right angles to each other for the correction of astigmatism
Ulcerative keratitis	An infected corneal ulcer
UV (Ultraviolet)	Light from the sun that can be harmful to the eye

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	See Instruction Leaflet
	Use By Date (expiration date)
	Batch Code
	Sterile Using Steam or Dry Heat
	Diameter
	Base Curve
	Diopter (lens power)
	UV Blocking
	Fee Paid for Waste Management
	Peel Back Foil
	Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner
	Center Thickness
	Visibility Tinted Lens Orientation Correct Visibility Tinted Lens Inside Out
	Cylinder Power Axis
LOW	"Low" near ADD
MID	"Medium" near ADD
HIGH	"High" near ADD

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, Florida 32256
1-800-843-2020
www.acuvue.com

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AT 11 09 01
Date 09/09

Johnson & Johnson
Vision Care, Inc.

510(k) Premarket Notification

VISTAKON® (narafilcon B) Contact Lens
For Single Use Daily Wear Only

Volume 2 of 3

February 8, 2010

Table of Contents

	Page Number
VOLUME 1	
1 - Medical Device User Fee Cover Sheet	2
2 - CDRH Premarket Review Submission Cover Sheet	5
- ClinicalTrials.gov	14
- Reviewer Checklists	16
3 – 510(k) Cover Letter	31
4 - Indications for Use Statement	33
5 - 510(k) Summary	35
6 - Truthful and Accuracy Statement	42
7 – Class III Summary and Certification	44
8 - Financial Certification	45
9 - Declaration of Conformity and Summary Reports	47
10 - Executive Summary	64
11 - Device Description	71
12 - Substantial Equivalence Discussion	82
13 – Proposed and Predicate Labeling	88
14 - Sterilization and Shelf Life	92
15 – Biocompatibility	97
16 – Software	102
17 - Electromagnetic Compatibility and Electrical Safety	103
18 - Performance Testing – Bench	104
19 - Performance Testing – Animal	107
20 - Performance Testing – Clinical	108
21 – Other	112
Attachment A – Engineering Drawings	A
Attachment B – Manufacturing Flow Chart	B
Attachment C – Shelf Life Protocol	C
Attachment D – MSDS	D
Attachment E – Biocompatibility Reports	E
Attachment F – USAN	F
Attachment G – Proposed Labeling	G
VOLUME 2	
Attachment H – Clinical Study Report	H
VOLUME 3	
Attachment H – Clinical Study Report (continued)	H-294
Attachment I – Standard Data Summary Reports	I

Attachment H – Pivotal Clinical Study

Contents

This attachment contains the Pivotal Clinical Study Report.

Continued on next page

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VISTAKON® Investigational Contact Lens (narafilcon(b)(4)) Worn as Single Use Daily Wear

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Johnson & Johnson
Vision Care, Inc.

510(k) Premarket Notification

VISTAKON® (narafilcon B) Contact Lens
For Single Use Daily Wear Only

Volume 3 of 3

February 8, 2010

Table of Contents

	Page Number
VOLUME 1	
1 - Medical Device User Fee Cover Sheet	2
2 - CDRH Premarket Review Submission Cover Sheet	5
- ClinicalTrials.gov	14
- Reviewer Checklists	16
3 – 510(k) Cover Letter	31
4 - Indications for Use Statement	33
5 - 510(k) Summary	35
6 - Truthful and Accuracy Statement	42
7 – Class III Summary and Certification	44
8 - Financial Certification	45
9 - Declaration of Conformity and Summary Reports	47
10 - Executive Summary	64
11 - Device Description	71
12 - Substantial Equivalence Discussion	82
13 – Proposed and Predicate Labeling	88
14 - Sterilization and Shelf Life	92
15 – Biocompatibility	97
16 – Software	102
17 - Electromagnetic Compatibility and Electrical Safety	103
18 - Performance Testing – Bench	104
19 - Performance Testing – Animal	107
20 - Performance Testing – Clinical	108
21 – Other	112
Attachment A – Engineering Drawings	A
Attachment B – Manufacturing Flow Chart	B
Attachment C – Shelf Life Protocol	C
Attachment D – MSDS	D
Attachment E – Biocompatibility Reports	E
Attachment F – USAN	F
Attachment G – Proposed Labeling	G
VOLUME 2	
Attachment H – Clinical Study Report	H
VOLUME 3	
Attachment H – Clinical Study Report (continued)	H-294
Attachment I – Standard Data Summary Reports	I

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Attachment A: Informed Consent

Study Title	VISTAKON® Investigational Contact Lens (narafilcon (b)(4)) Worn as Single Use Daily Wear

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CONFIDENTIAL

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Attachment I – Standards Data Summary Reports

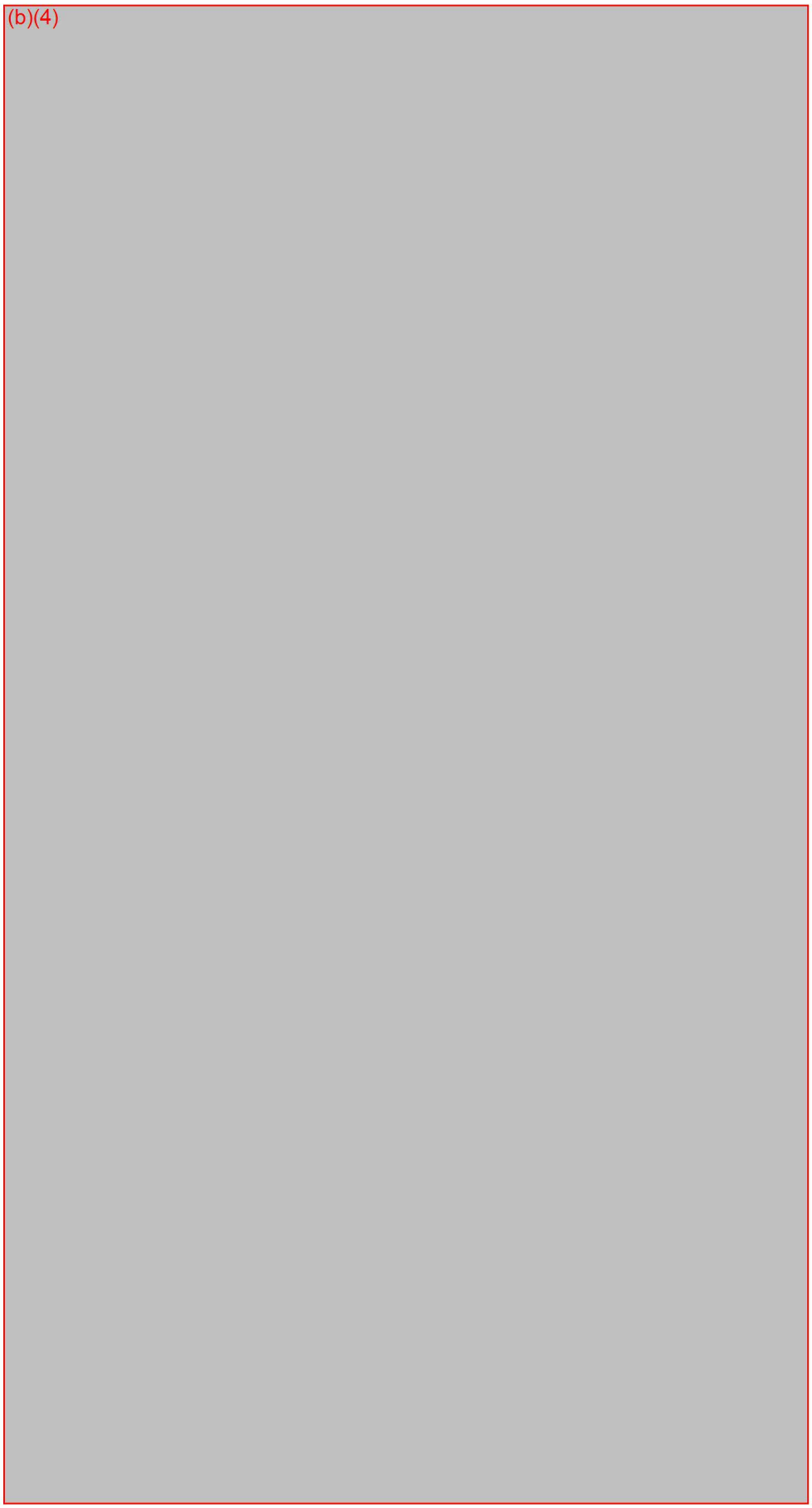
Contents

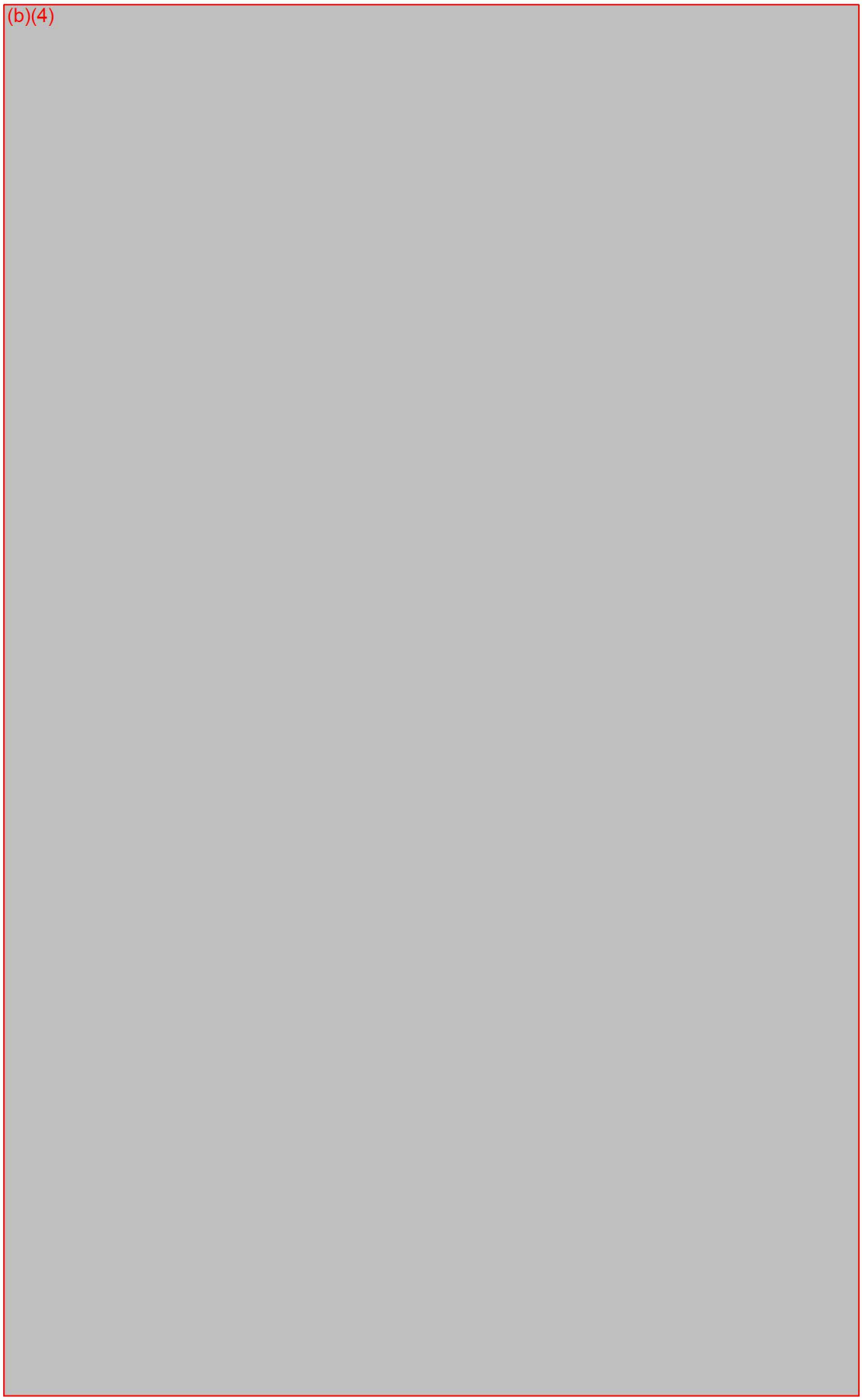
This attachment contains the Standards Data Summary Reports for the following standards:

(b)(4)

Continued on next page

Standards Data Summary Report for 510(k)s

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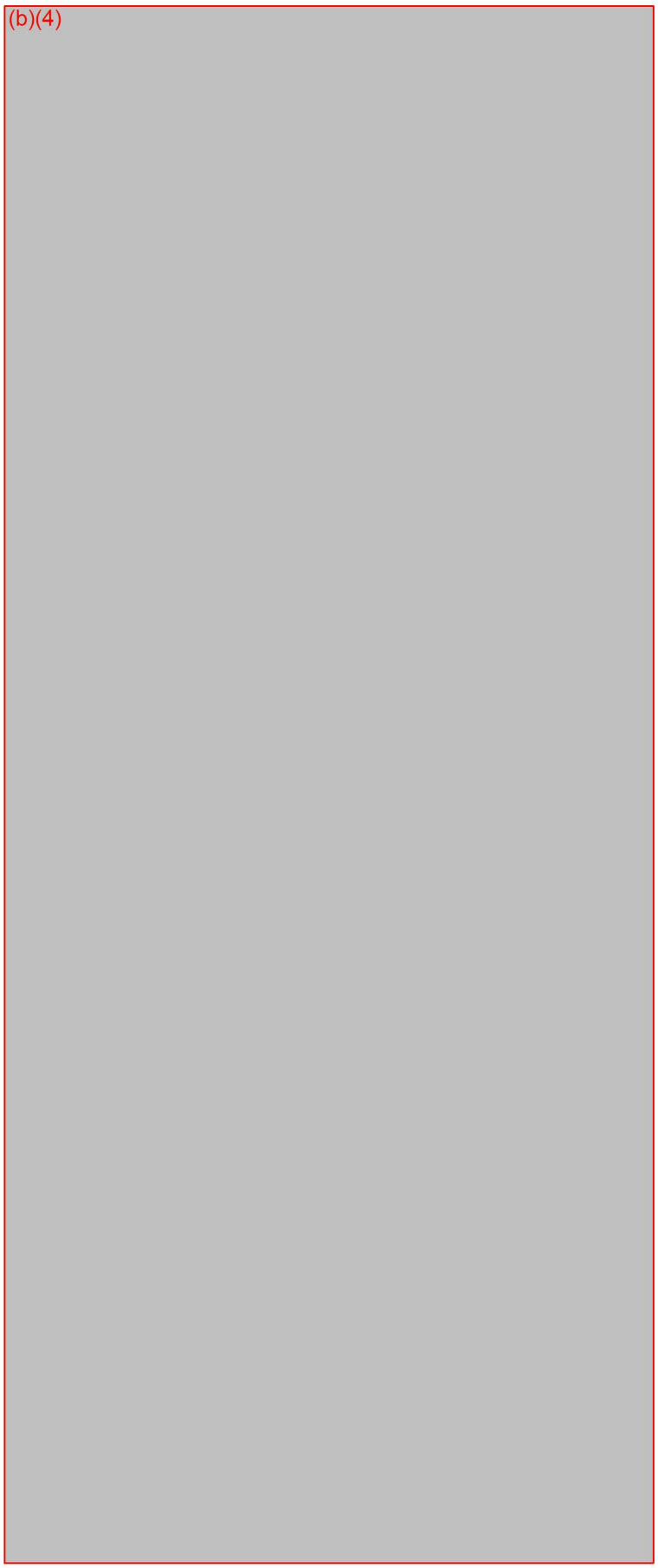
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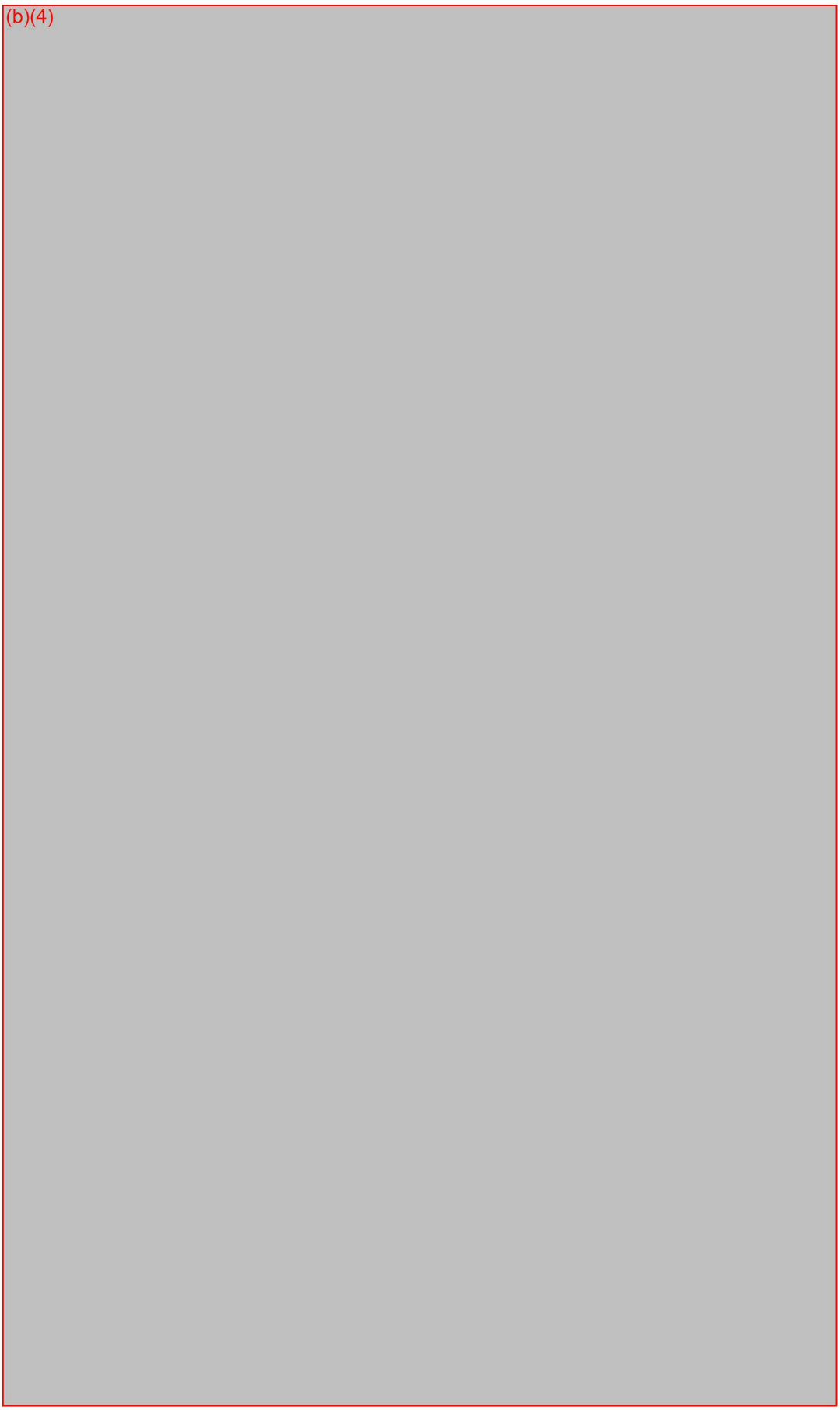
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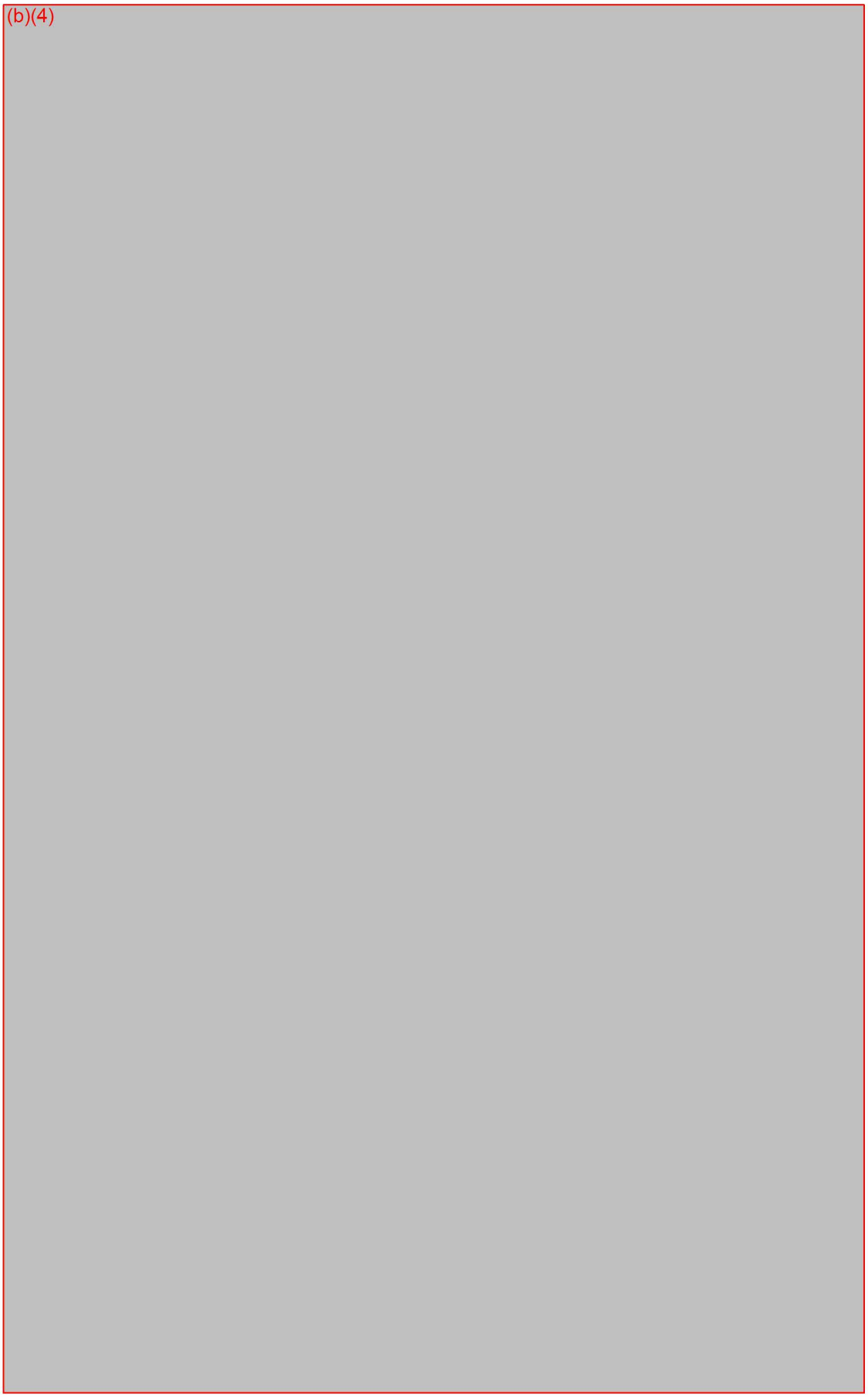
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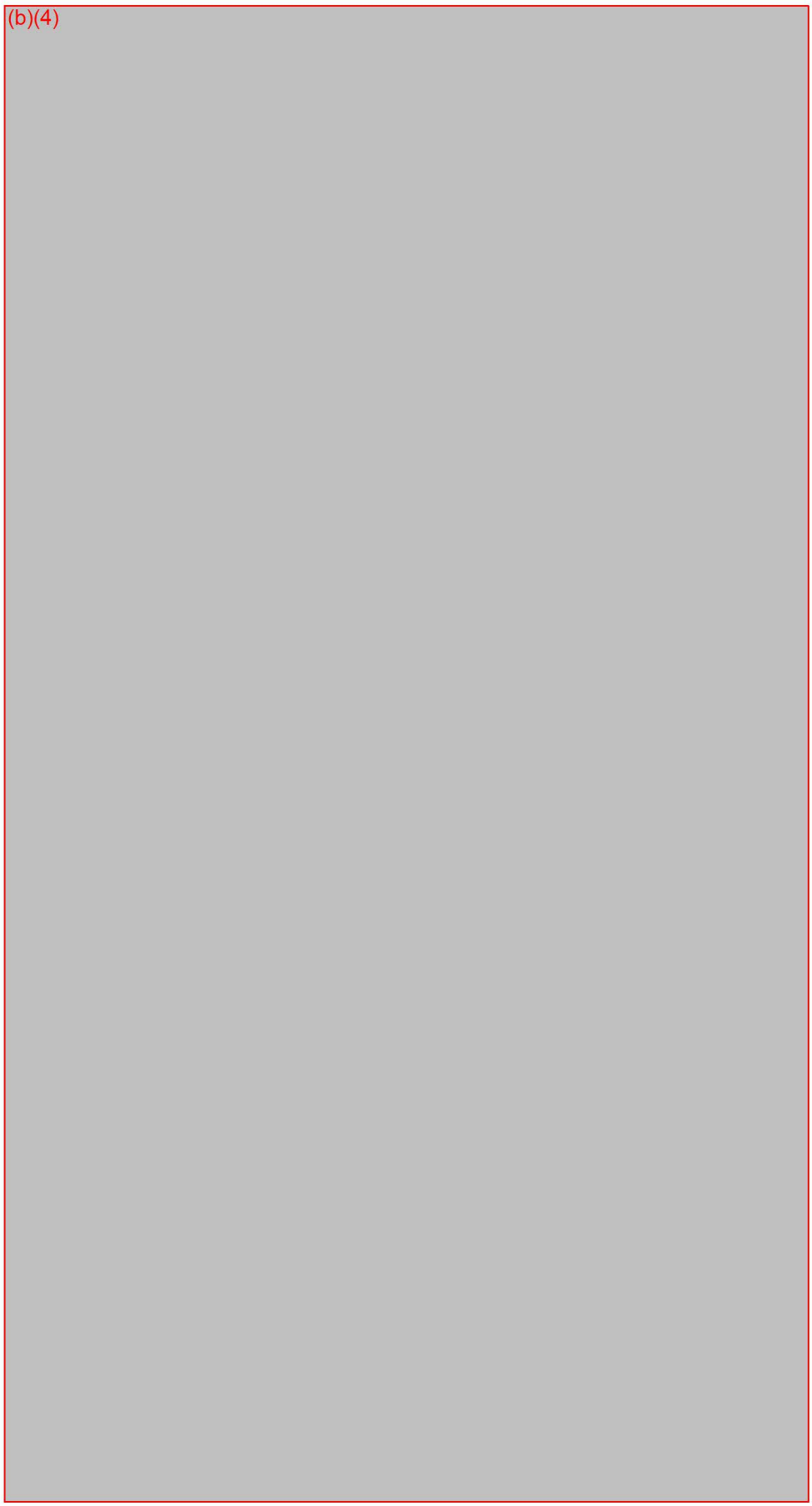
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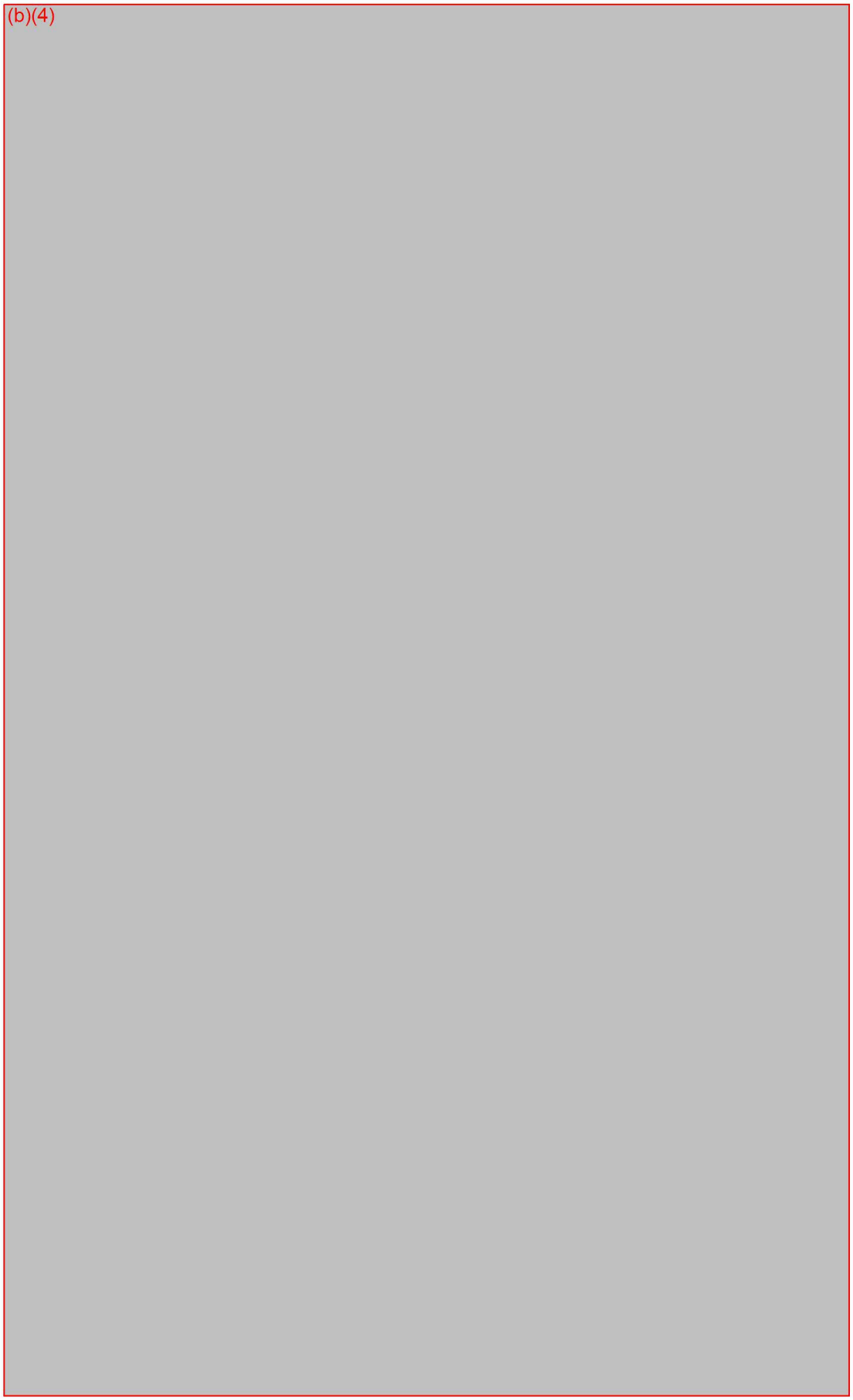
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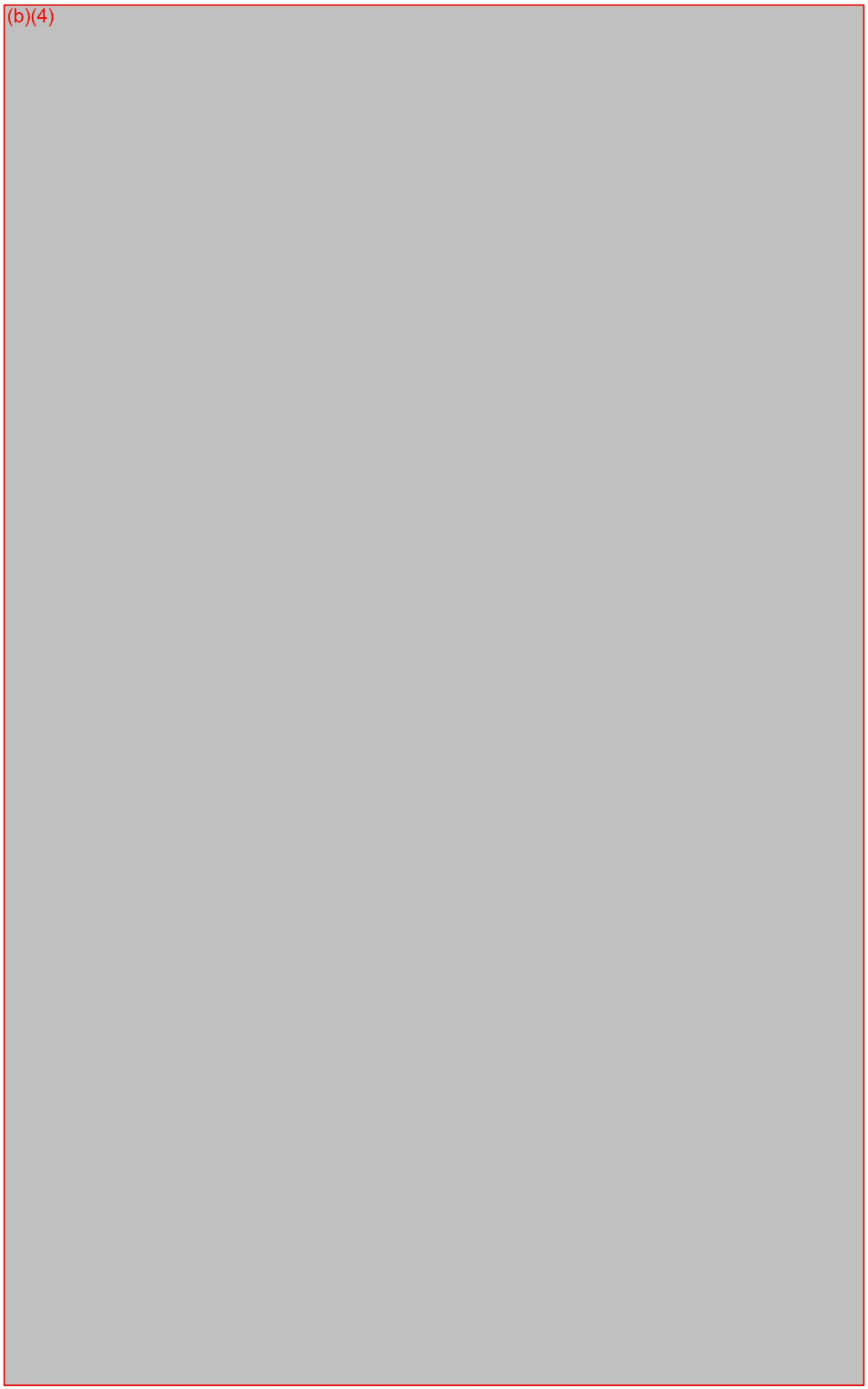
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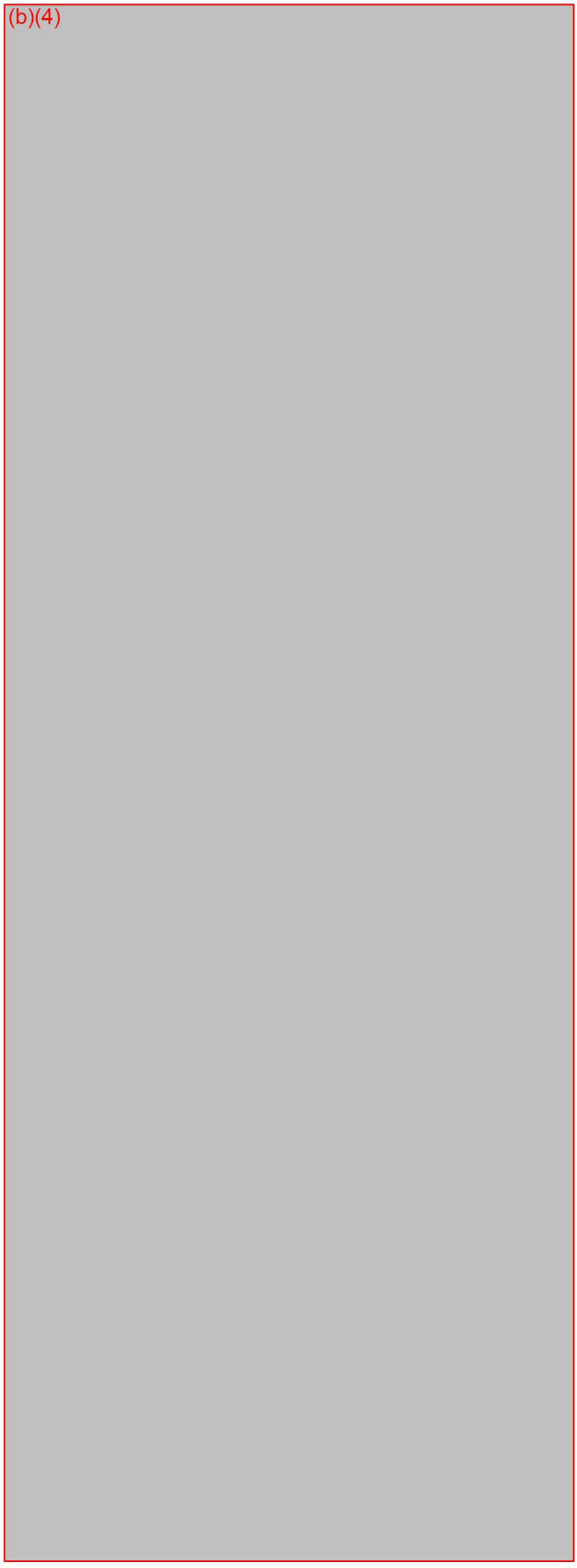
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Standards Data Summary Report for 510(k)s

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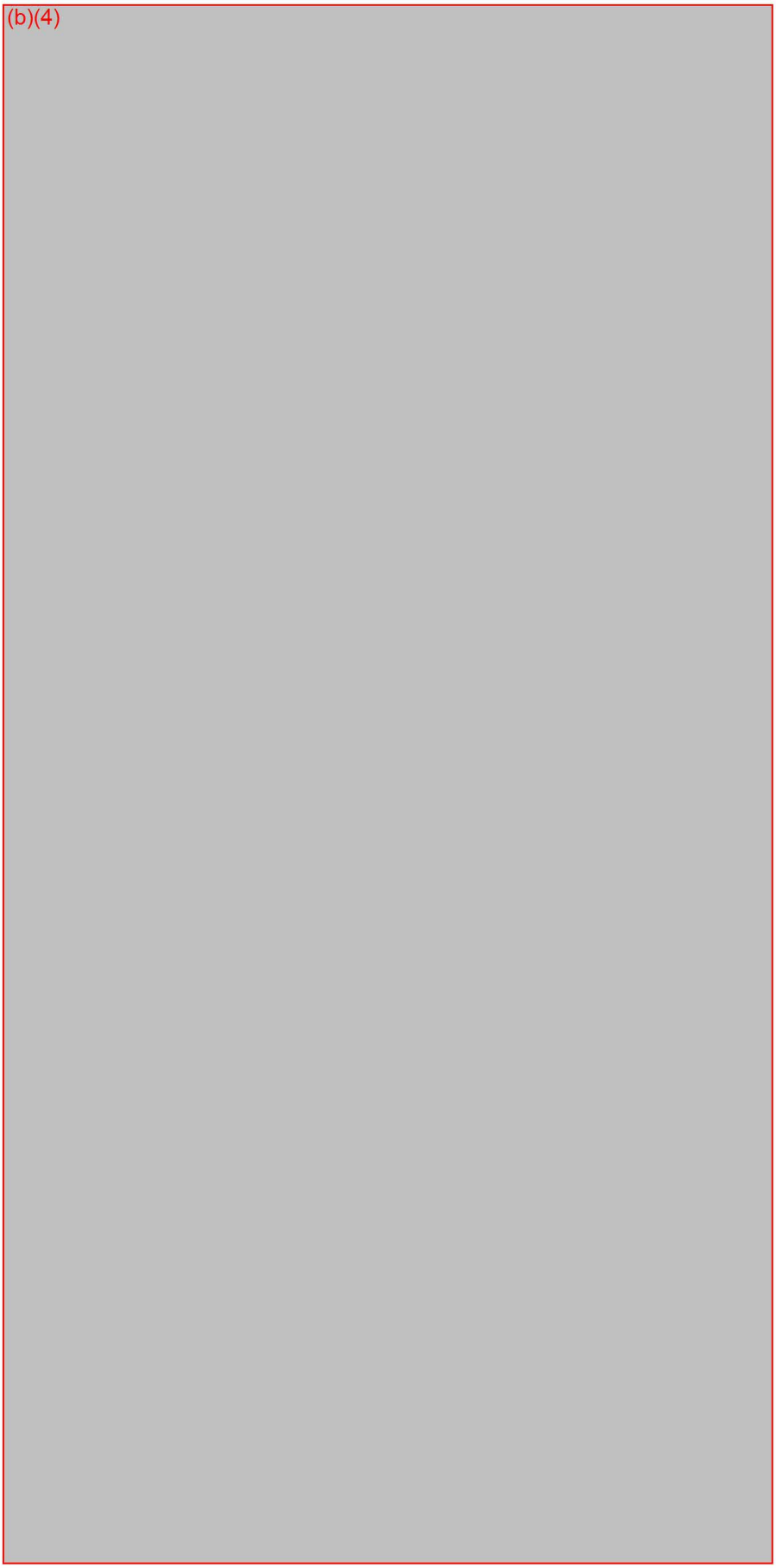
Standards Data Summary Report for 510(k)s



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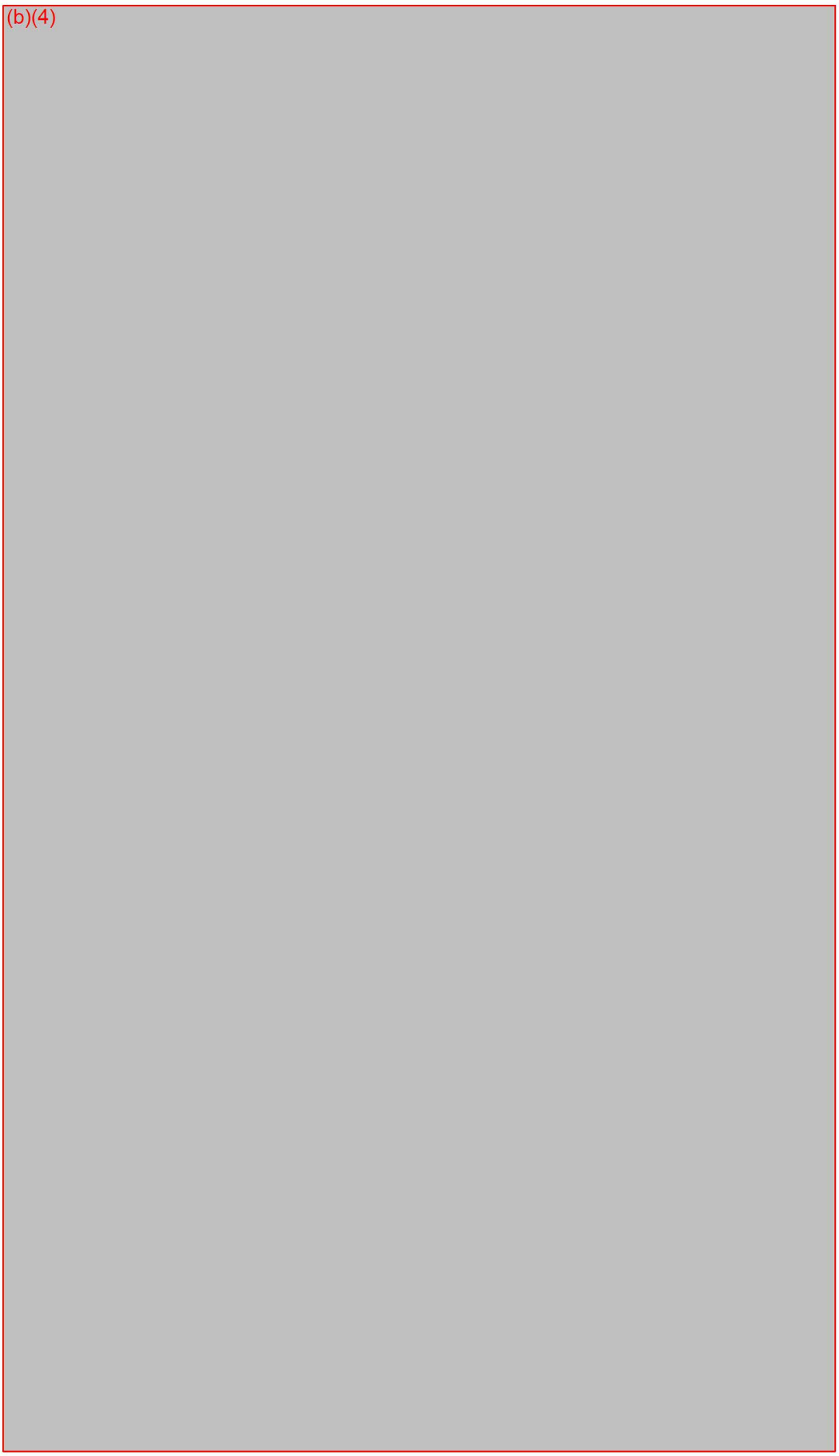

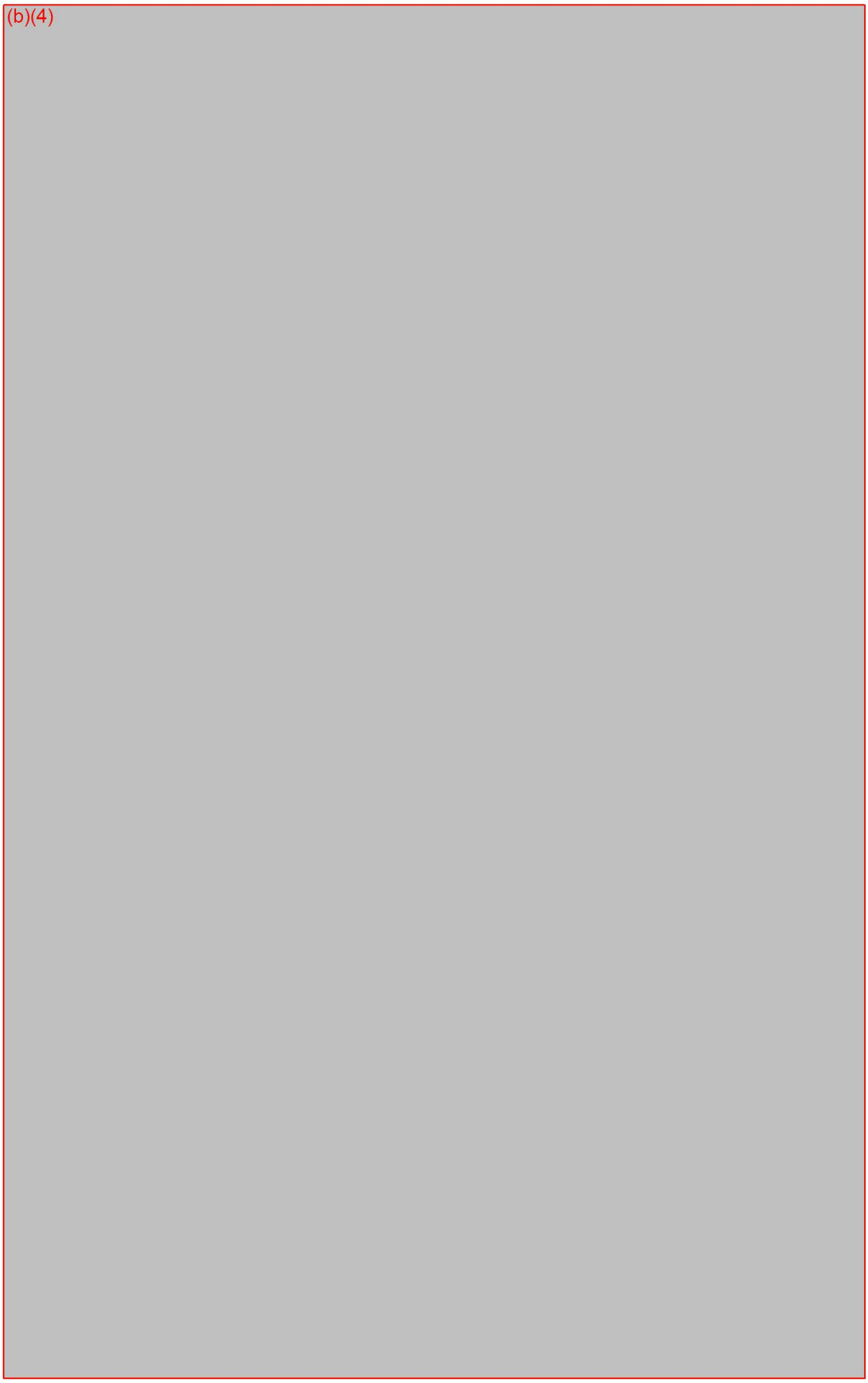
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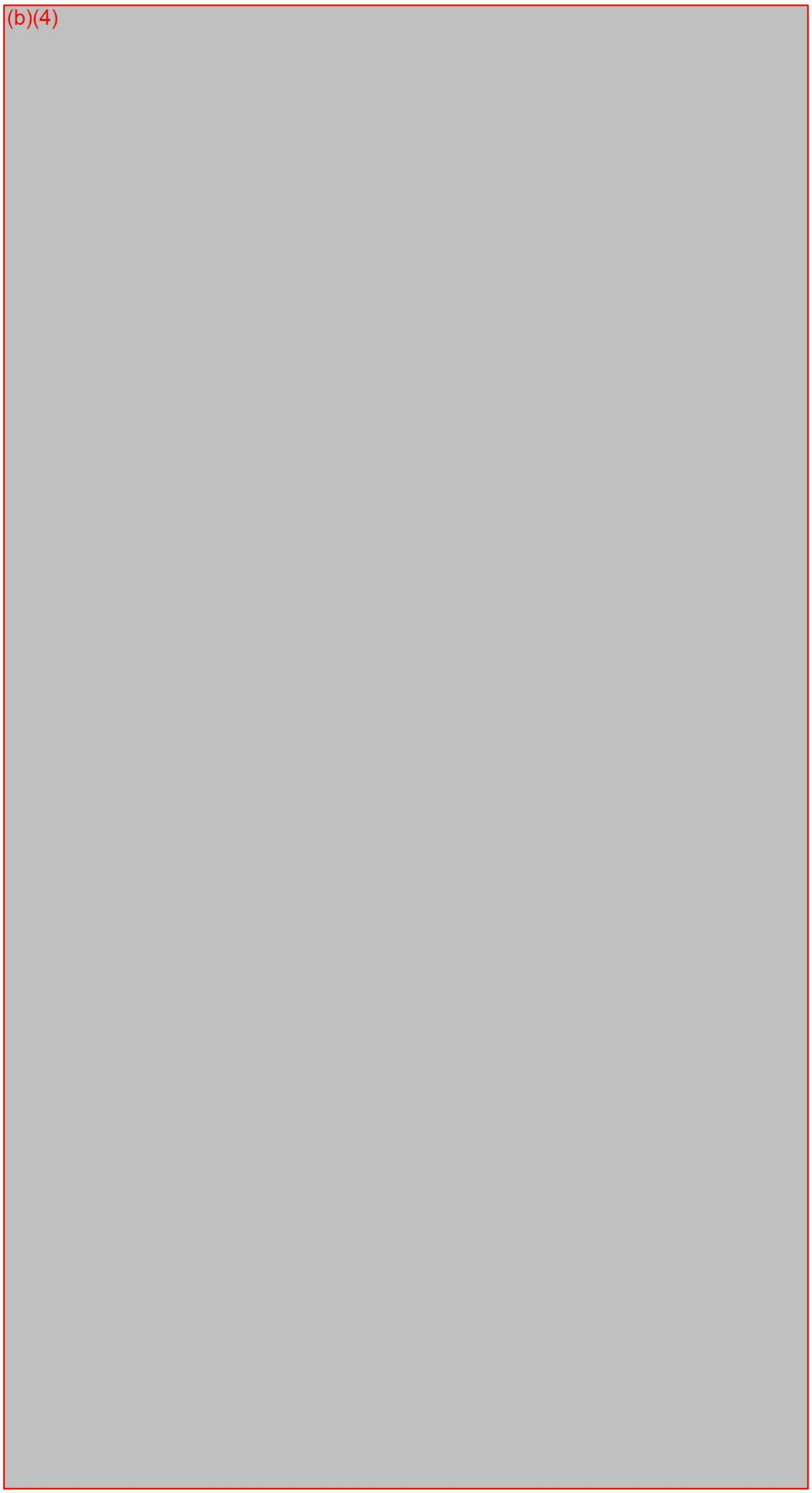
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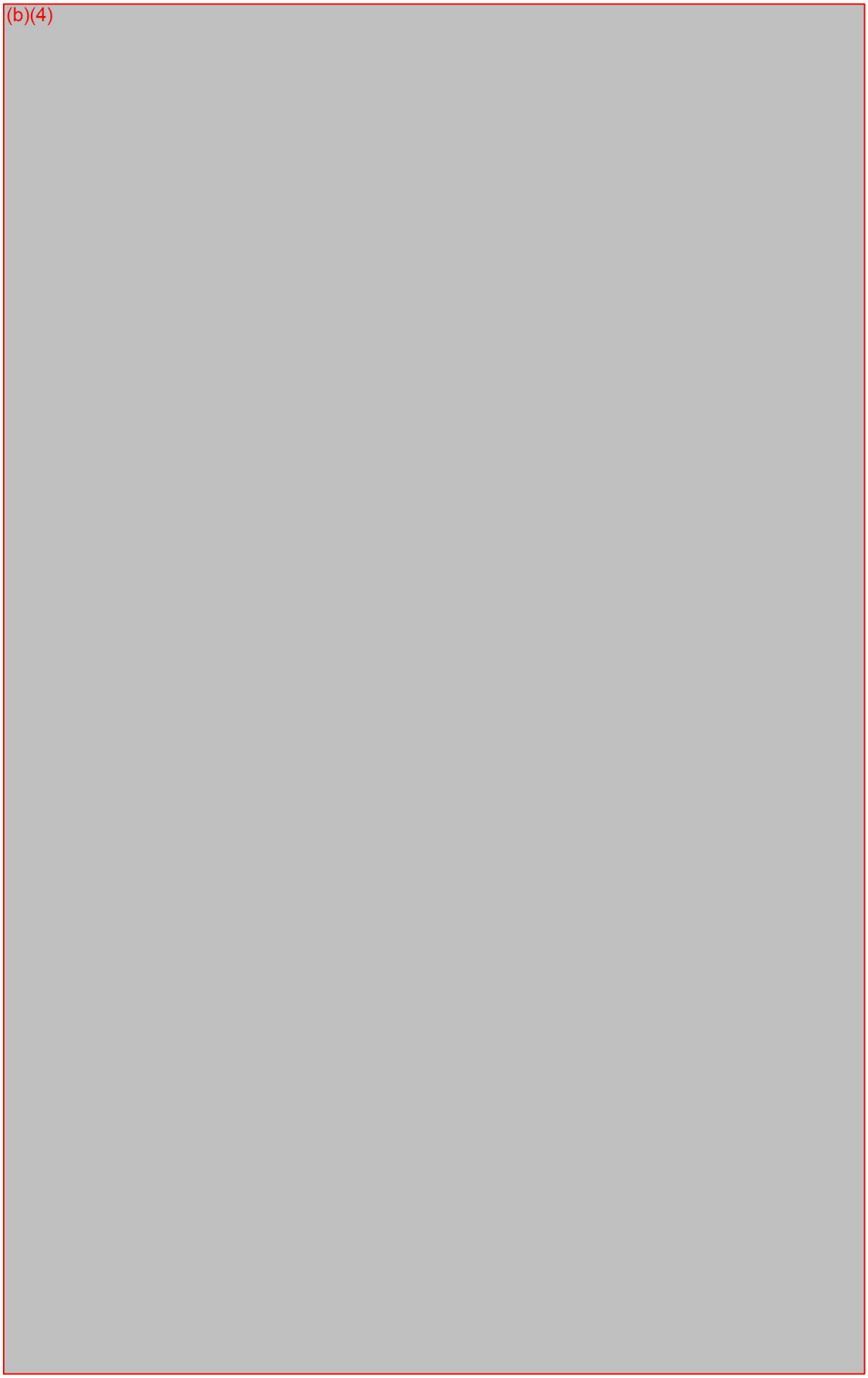
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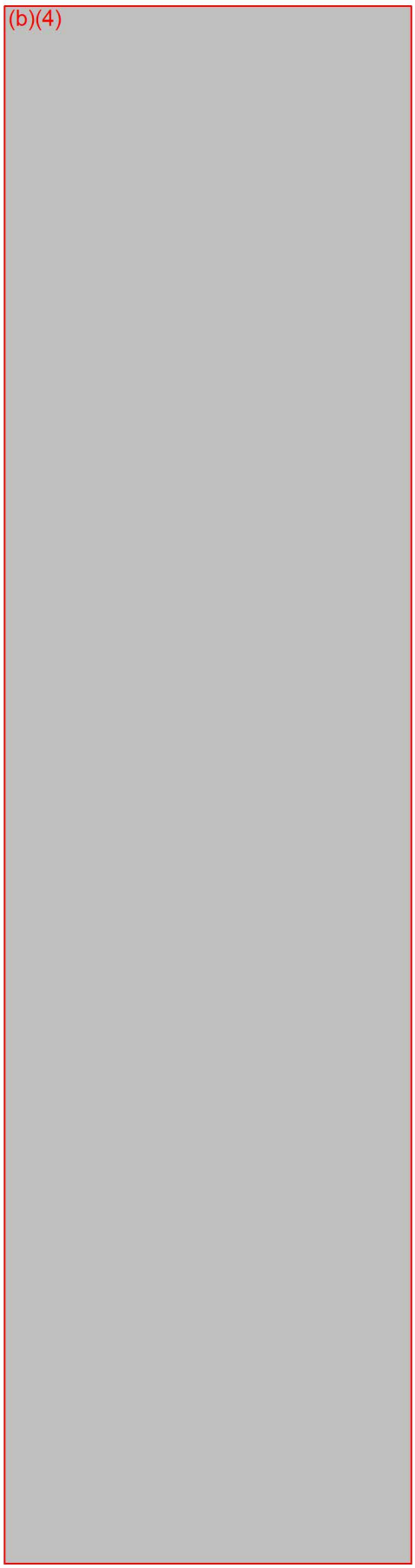
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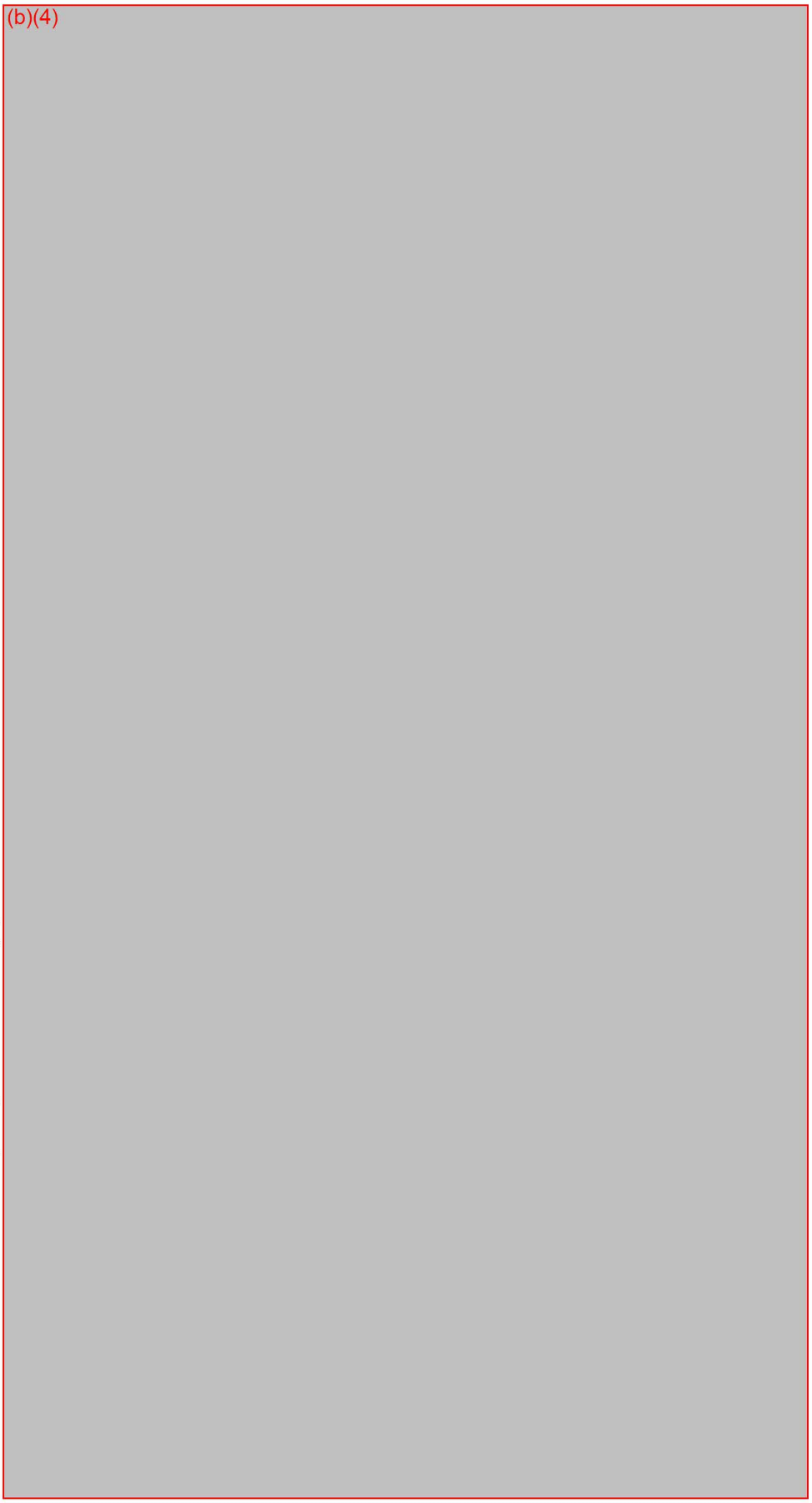

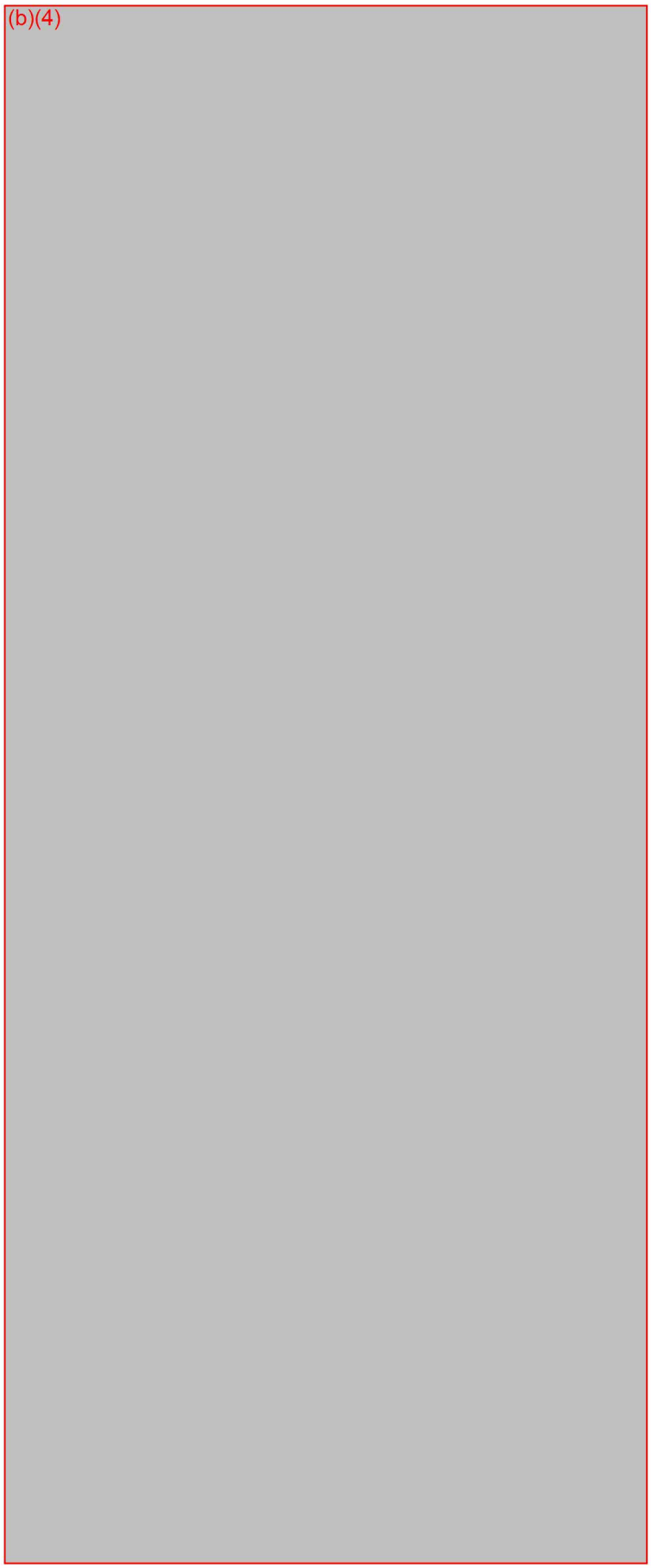
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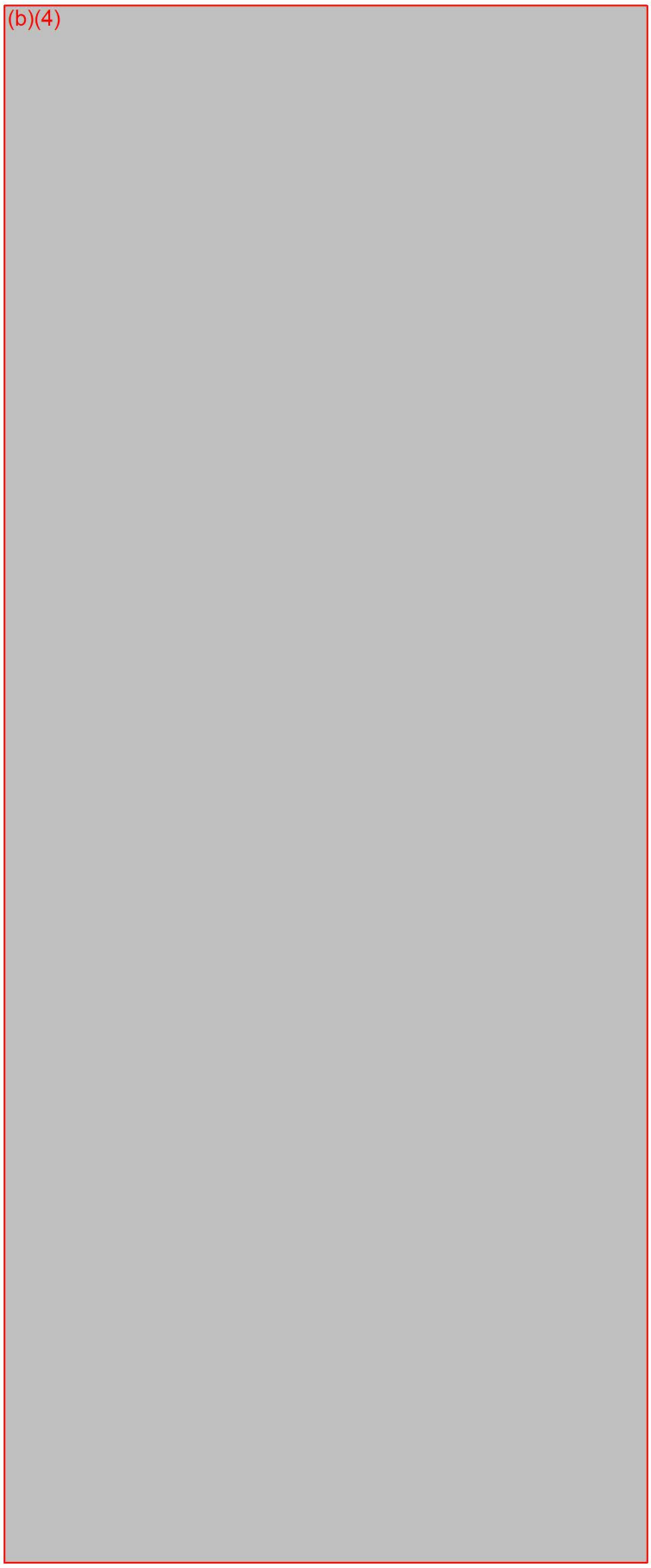
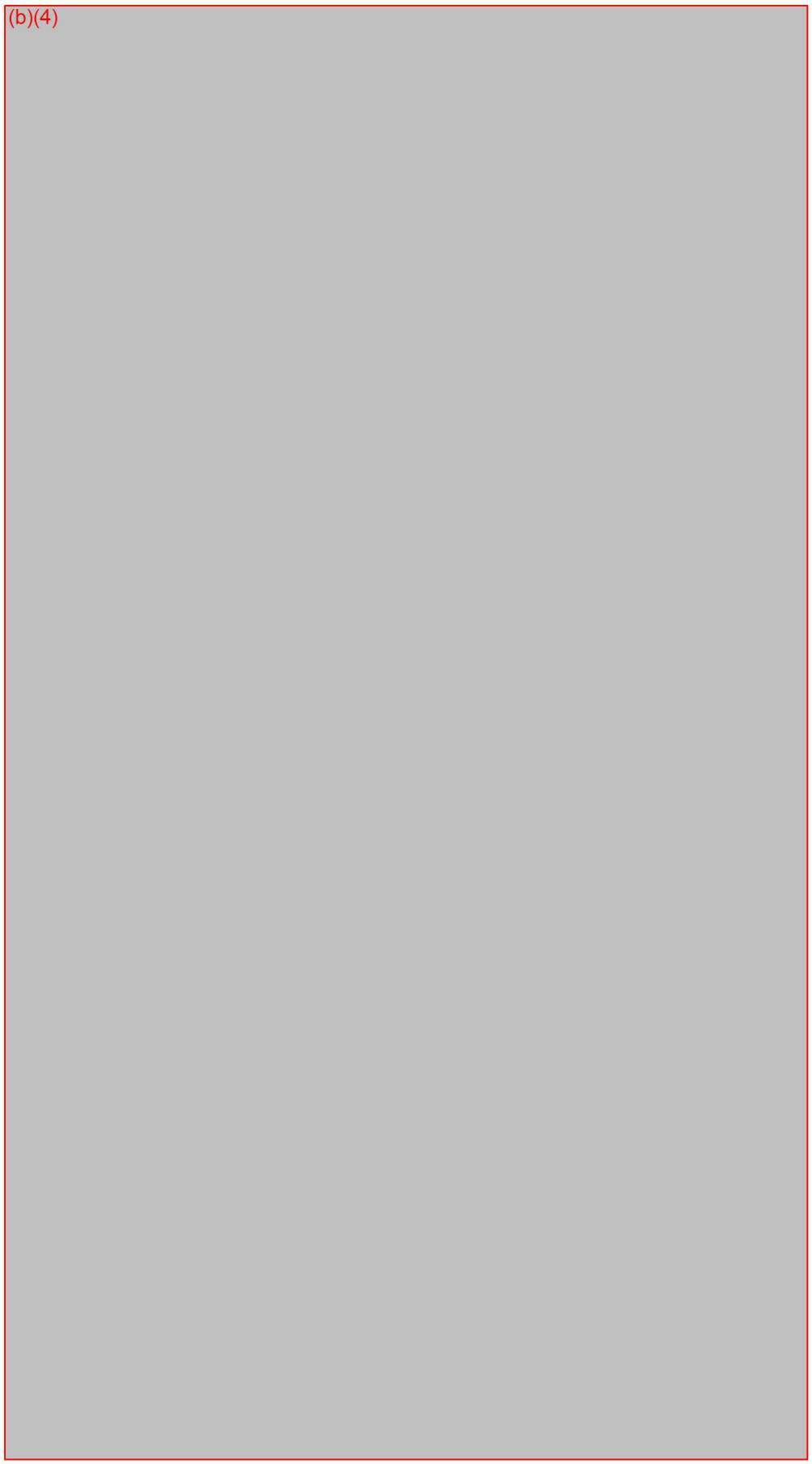
Standards Data Summary Report for 510(k)s



Standards Data Summary Report for 510(k)s



Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Karen Warburton

Subject: 510(k) Number K100349/S1

To: The Record

Please list CTS decision code SE

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☐ Hold (Additional Information or Telephone Hold).
- ☒ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			NO
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)		✓	
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC*

Regulation Number	Class*	Product Code
886.5925	II	LPL

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____ (Branch Chief) ICVB (Branch Code) 5/20/10 (Date)

Final Review: Kevin Alexander for (Division Director) 5/21/10 (Date)

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K100349

Date: May 20, 2010
To: The Record
From: Karen Warburton

Office: ODE
Division: DONED

510(k) Holder: Johnson & Johnson Vision Care, Inc.
Device Name: VISTAKON® (narafilcon B) Contact Lens Visibility Tinted, with UV Blocker
Contact: Catherine Dillon
Phone: (904) 443-3180
Fax:
Email: cdillon9@its.jnj.com

I. Purpose and Submission Summary

To submit a premarket notification for the narafilcon B daily wear contact lens. (The narafilcon A contact lens was previously cleared.)

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	✓		
Truthful and Accuracy Statement	✓		
510(k) Summary or 510(k) Statement	✓		
Standards Data Report Form – Form 3654 1: No standard used - No Standards Form Required 2: Declaration of Conformity - Yes Standards Form Required 3: Standard but no declaration - Yes Standards Form Required	✓		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		✓	
Is the device an implant (implanted longer than 30 days)?		✓	
Does the device design use software?		✓	
Is the device sterile?	✓		
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		✓	

7

IV. Indications for Use

The VISTAKON® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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.

V. Predicate Device Comparison

See attached chemistry reviews.

VI. Labeling

A package insert and fitting and patient management guide, patient instruction guide, primary and secondary labels were provided. All contain the appropriate information.

VII. Sterilization/Shelf Life/Reuse

See attached chemistry and microbiology reviews.

VIII. Biocompatibility

See attached biocompatibility review.

IX. Software: NA

Version:		
Level of Concern:		
	Yes	**No**
Software description:		
Device Hazard Analysis:		

Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety: NA

XI. Performance Testing – Bench

See attached chemistry review.

XII. Performance Testing – Animal

See attached biocompatibility review.

XIII. Performance Testing – Clinical

See attached clinical reviews.

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	✓		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?		✓	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	✓		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		✓	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	✓		If **NO** = Stop **NSE**
8. Performance Data Available?	✓		If **NO** = Request Data
9. Data Demonstrate Equivalence?	✓		Final Decision: SE

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics: new(modified) material – nasafilconB

4. Explain how new characteristics could or could not affect safety or effectiveness: new material may have effect on biocompatibility

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new: Same biocompatibility, effectiveness questions

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: preclinical or clinical data provided demonstrate equivalence. See attached reviews.

XV. Deficiencies

When developing deficiencies please consider the following "Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA" (http://www.fda.gov/cdrh/modact/guidance/1195.html) and "A Suggested Approach to Resolving Least Burdensome Issues" (http://www.fda.gov/cdrh/modact/leastburdensome.html).

XVI. Contact History

NA – previous AI (telephone hold/email)

XVII. Recommendation

Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL

Karen Warburton
Reviewer

5/20/10
Date

Branch Chief

5/20/10
Date

Date: May 20, 2010

From: Karen Warburton, Microbiologist and Team leader Karen Warburton

Subject: K100349/S001 Vistakon (narafilcon B) Contact Lens Visibility Tinted with UV Blocker– Team leader and Microbiology review

To: The Record
Through: Chief, Intraocular, Corneal and Neuromaterials Branch
Tina Kiang, Ph.D. 5/20/10

Supplement 1 responds to the request for additional information that was emailed to the sponsor on April 26, 2010.

Ming Shih reviewed the sponsor's responses to deficiencies #3 though #9 and found all responses to be adequate. She recommends a substantial equivalence decision from a chemistry perspective.

Marc Robboy, O.D. reviewed the sponsor's response to deficiency #10 and recommends a substantial equivalence decision from a clinical perspective.

Review of sponsor's responses to deficiencies #1 and #2

Deficiency 1: You provide indications for use for the multifocal, toric, and multifocal toric lens designs; however, you do not describe the ADD power ranges. Please revise the indications for use o include the ADD power and cylinder ranges for the multifocal, toric, and multifocal toric lenses and provide modified labeling, indications for use form and a 510(k) summary that includes the revised indications.

Sponsor's response: The ADD power ranges were added for the multifocal and toric multifocal lenses. The indications for use previously included the cylinder ranges.

Reviewer's comment: Adequate response. The sponsor has also included revised indications for use form, 510(k) summary, and labeling that includes the complete indications.

Deficiency 2: You state that (b)(4) *studies to demonstrate* (b)(4) *were performed. However, you do not describe the specific* (b)(4) (b)(4)

Sponsor's response: (b)(4)
(b)(4)

Reviewer's comment: *Adequate response.*

Conclusion/recommendation: SUBSTANTIALLY EQUIVALENT

The sponsor has provided adequate information in response to our additional information request. A substantial equivalence decision is recommended.

K100349/S001
510(k) Clinical Review: Response to Deficiencies

Date: May 17, 2010

From: **Marc Robboy** Marc Robboy

To: Karen Warburton, Team Leader

Subject: 510(k) Clinical Review

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

Contact:
Catherine C. Dillon
Project Leader I
Regulatory Affairs
Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Suite 100
Jacksonville, FL 32256
904-443-3180
cdillon9@its.jnj.com

Introduction:
This submission contains the sponsor's responses, received May 5, 2010, to the April 26, 2010 FDA request for additional information. The single clinical deficiency is listed below, along with the sponsor's response, which was presented in their submission.

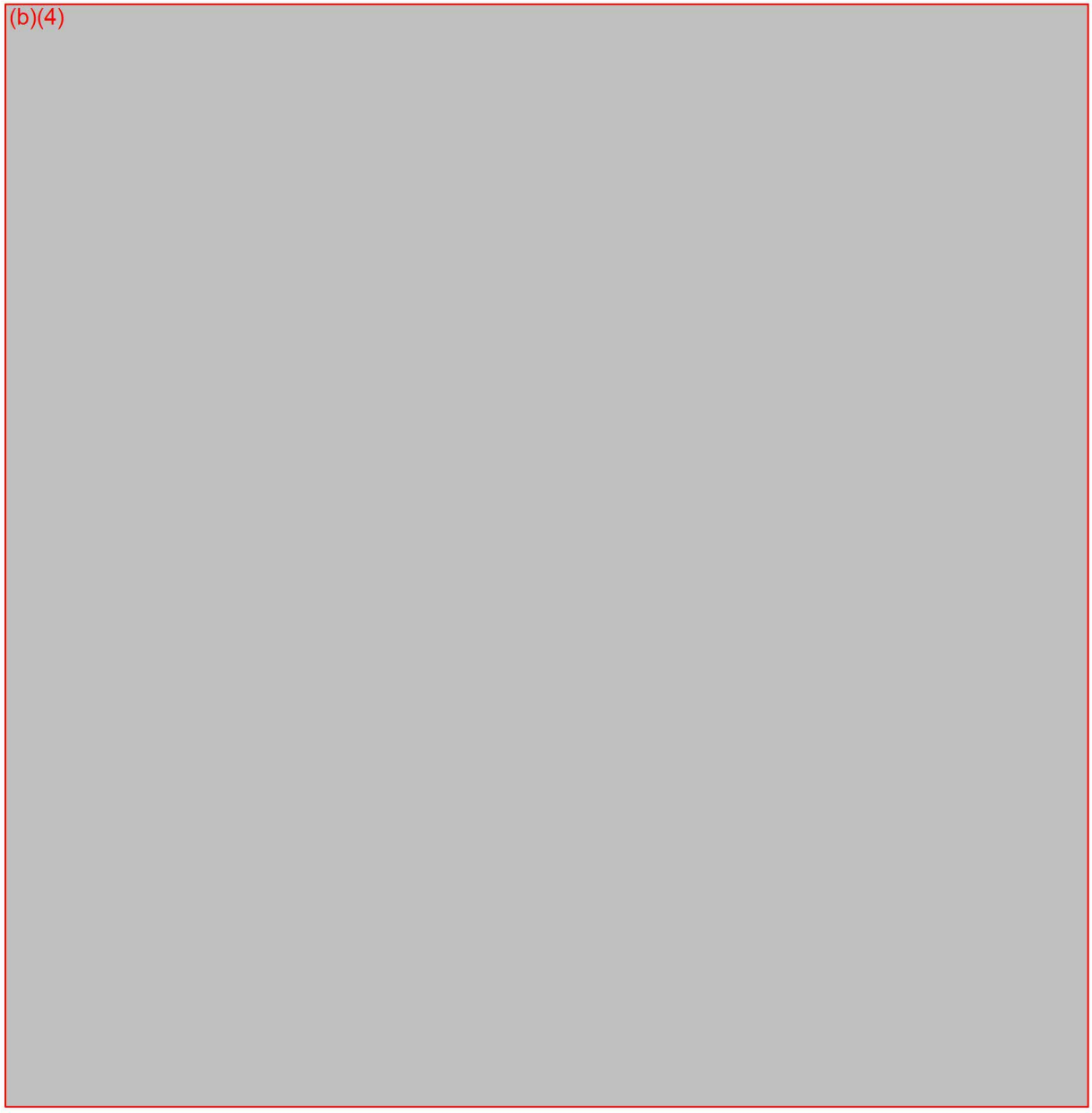
10. For your clinical study you report (b)(4)

(b)(4)

Sponsor Response:

(b)(4)

(b)(4)



(b)(4)

Reviewer Comment:

(b)(4)

Conclusion/Recommendation:
The sponsor has addressed my only deficiency in an acceptable manner. I recommend clearance for this device, from a clinical perspective.

Memorandum

Date: May 19, 2010

From: Ming-chuen Shih, Chemist, ICNB/DONED

Subject: Chemistry Review for K100349 from Johnson & Johnson Vision Care, Inc
Device Trade Name: VISTAKON® (narafileon B) Contact Lens

To: Records through Karen Warburton, Team Leader

Introduction

Johnson & Johnson Vision Care, Inc. (the Company), submits this premarket notification for the VISTAKON® (narafilcon B) Contact Lens Visibility Tinted, with UV Blocker.

Device Description

- The VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV blocker is available as a spherical lens, a multifocal lens, a toric lens and a multifocal-toric lens.
- The lenses are made of a silicone hydrogel material containing an internal wetting agent.
- The VISTAKON® (narafilcon B) Contact Lens may be 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® (narafilcon 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% narafilcon B and 48% water by weight when hydrated and stored in the buffered saline solution.

Indications for Use

The VISTAKON® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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.

Predicate devices

Material
VISTAKON® (narafilcon A) Contact Lens – K073485
(FDA Group I; low water, nonionic polymer)
Indication, Wear Schedule
VISTAKON® (etafilcon A) Contact Lenses – K962804
(Daily wear, single use)(*Reviewer's note: This is a Group IV lens: high water, ionic polymer)*

Note: The VISTAKON® (narafilcon A) Contact Lens has not been marketed in the United States.

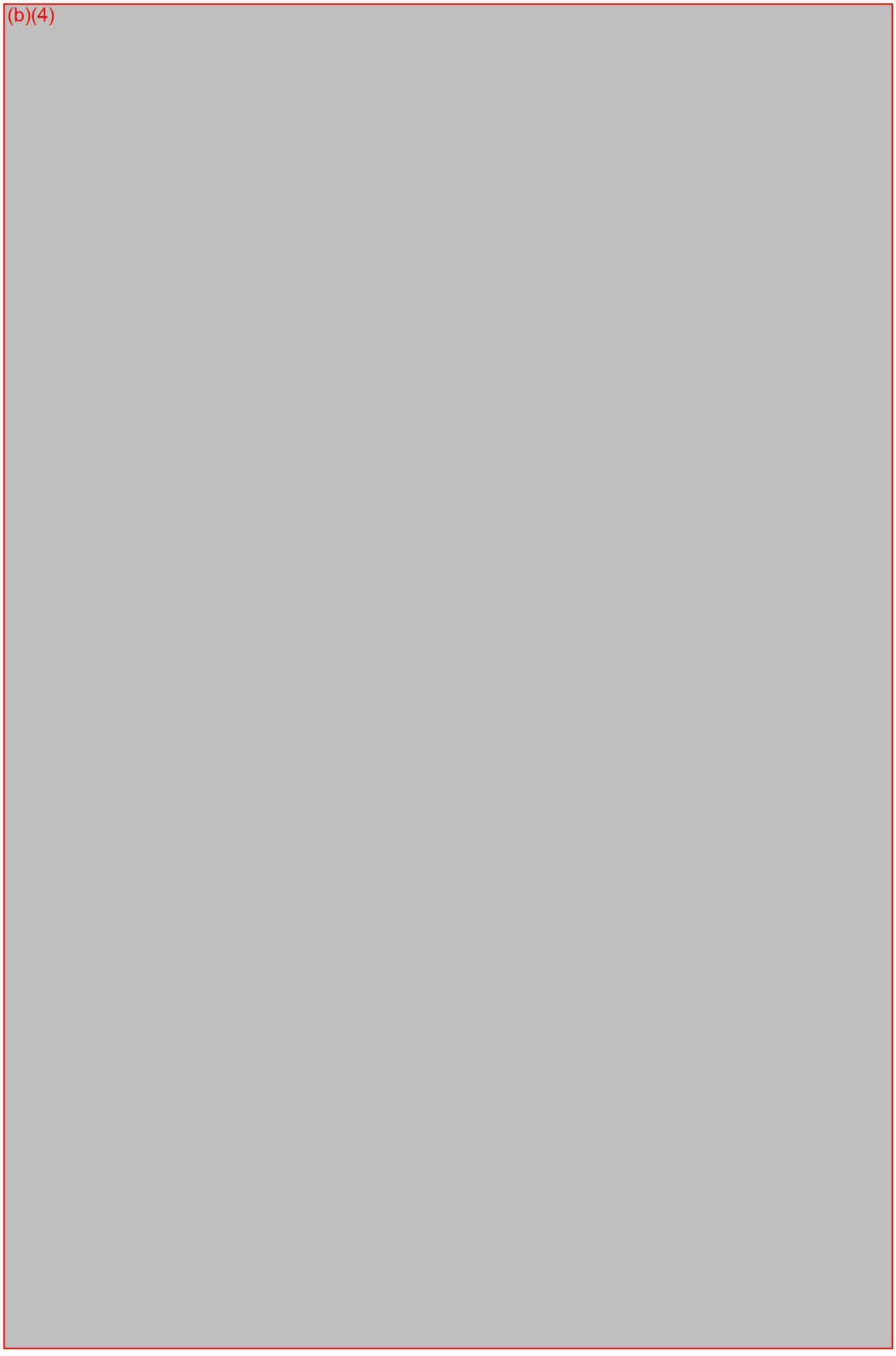
After we had reviewed the original submission, this 510(k) was put on telephone hold with an e-mail which conveyed the identified deficiencies to be addressed. This review covers the responses to Deficiencies (b)(4) In the following review the cited deficiency is re-iterated followed by the Company's response and this reviewer's comment.

Review

3. (b)(4)

Response:
(b)(4)

17



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(b)(4)

Response adequate.

4. (b)(4)

Response:

(b)(4)

Response adequate.

5. (b)(4)

Response:

(b)(4)

Response adequate.

6. (b)(4)

Response:

(b)(4)

(b)(4)

Response adequate.

7. (b)(4)

Response:

(b)(4)

Response adequate.

8. (b)(4)

(b)(4)

Response:

(b)(4)

Response adequate.

9. (b)(4)

Response:

(b)(4)

Response adequate.

Recommendation

There are no pending chemistry issues. Clearance for marketing the subject device of this 510(k) is recommended from a chemistry perspective.

File name: k100349S001 Chemistry Review.doc

Warburton, Karen

ɔm:	Warburton, Karen
nt:	Monday, April 26, 2010 2:40 PM
o:	'cdillon9@its.jnj.com'; 'jzimovan@its.jnj.com'
Cc:	Kiang, Tina
Subject:	K100349 Additional information request

Re: K100349
Trade Name: Acuvue® TruEye™ (narafilcon B) Contact Lens
Dated: February 8, 2010
Received: February 12, 2010

Dear Ms. Dillon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information:

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The deficiencies identified above 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 (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the vice without conforming to these requirements, you will be in violation of the Act. You may, however, stribute this device for investigational purposes to obtain clinical data if needed to establish substantial uivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).
If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at **http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf**

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 additional information 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.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609

10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

ease note that the 510(k) will be placed on hold pending your response to this request for additional formation.

Karen

Karen Warburton, MT, MHS
Microbiologist
Intraocular, Corneal, and Neuromaterials Branch (ICNB)
Division of Ophthalmic, Neurological and ENT Devices
Office of Device Evaluation
Center for Devices and Radiological Health

(301) 796-5620 ***NEW number***
karen.warburton@fda.hhs.gov

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DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service, Food and Drug Administration

Date: April 19, 2010

From: Karen Warburton, Microbiologist and Team leader

Subject: K100349 Vistakon (narafilcon B) Contact Lens Visibility Tinted with UV Blocker– Team leader and Microbiology review

To: The Record

Through: Chief, Intraocular, Corneal and Neuromaterials Branch
Tina Kiang, Ph.D. 4/26/10

Indications for use:

The VISTAKON® (narafilcon 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®(narafilcon 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®(narafilcon 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® (narafilcon 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® (narafilcon 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.

Reviewer's comments (b)(4)

(b)(4)

Device Description

The lens material is narafilcon B, a silicone hydrogel material that includes a visibility tint (Reactive Blue Dye #4) and a UV absorber (benzotriazole). The lens is 48% water with a Dk of (b)(4) The lens is molded and the sponsor states that the manufacturing process is the same as that for the narafilcon A lens, with the exception of the proportions of monomers in the formulation. The lens is packaged in a buffered saline solution containing methyl ether cellulose in a (b)(4) blister pack with (b)(4) lidstock. The same packaging system is used for all currently marketed Vistakon lenses.

Microbiology

The lenses are steam sterilized to a minimum sterility assurance level of 10^{-6}. The same sterilization method is used for all currently marketed Vistakon lenses. The sponsor states "The (b)(4)

Reviewer's comments *The sponsor does not describe the* (b)(4)

(b)(4)

Shelf-life

(b)(4)

Reviewer's comments *The shelf-life protocol is acceptable. The sponsor is correct—no additional shelf-life sterility testing is necessary.*

Labeling

Proposed labeling (primary, secondary, package insert and fitting and management guide, and patient instruction guide) was provided.

Reviewer's comments *The indications for use should be modified as noted above.*

Consulting reviews

A clinical review was performed by Marc Robboy, O.D. who identified (b)(4) that should be relayed to the sponsor.

A chemistry review was performed by Ming Shih, who identifies deficiencies that should be relayed to the sponsor.

A toxicology review was performed by Susanna Jones, who indicates that from a biocompatibility perspective the submission can be found to be substantially equivalent.

Team leader's comments *This lens is a new silicone hydrogel lens. The sponsor provided no* (b)(4)

Conclusion/recommendation

Additional information is necessary in order to complete review of this 510(k). The following request for information should be relayed to the sponsor.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Date: April 21, 2010

From: Karen Warburton, Microbiologist and Team leader Karen Warburton

Subject: K100349 Vistakon (narafilcon B) Contact Lens Visibility Tinted with UV Blocker– Team leader and Microbiology review--Addendum

To: The Record

Through: Chief, Intraocular, Corneal and Neuromaterials Branch
Tina Kiang, Ph.D. 4/21/10

Based on feedback from Drs. Kiang and Robboy, the additional information questions have been modified as follows.

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Warburton, Karen

om: Kiang, Tina
nt: Tuesday, April 20, 2010 4:08 PM
o: Warburton, Karen
Cc: Shih, Ming; Robboy, Marc
Subject: RE: K100349 AI

Importance: High

Please see edits. In addition, there appears to be deficiencies in both Ming's and Marc's reviews that were not included in this email. However, you did not explain why these deficiencies are not being relayed in your review, nor that the reviewers provided concurrence on not relaying these deficiencies. You also did not appear to address your own comment regarding (b)(4) your review. Please revise your review and add the additional deficiencies, or provide comment as to why they will not be included. Please provide a revised review and draft email for me to review.

Tina

From: Warburton, Karen
Sent: Monday, April 19, 2010 8:20 PM
To: Kiang, Tina; Shih, Ming; Robboy, Marc
Subject: K100349 AI

Here are the AI questions that I've drafted to be relayed to the sponsor (email). Please let me know if you have edits. Thanks.

ditional information is necessary in order to complete review of this 510(k). The following request for formation should be relayed to the sponsor.

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7. (b)(4)

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Warburton, Karen

om: Robboy, Marc
nt: Tuesday, April 20, 2010 11:08 AM
: Warburton, Karen
Subject: RE: K100349 AI

Hi Karen:
I reviewed some 510(k)s and you are correct that some IFU contain ranges fro multifocals, although some do not. However, some of the Torics do also:
Toric - Biomedics 55 (ocufilcon D) TORIC Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and nonaphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters **and astigmatic corrections from -0.25 to -10.00 diopters.**

So to be consistent if we are asking for a Multifocal range we should also request a Toric range, don't you agree?
Marc

Marc Robboy, OD
Marc Robboy/ Optometrist/ Clinical Reviewer
US Food & Drug Administration/ Center for Devices and Radiological Health
Division of Ophthalmic, Neurological and ENT Devices
Intraocular, Cornea and Neuromaterials Branch

White Oak Building 66, Room 2256
`903 New Hampshire Avenue
.ver Spring, MD 20993
one: 301.796.6860
. ax: 301.847.8126
Email: marc.robboy@fda.hhs.gov

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From: Robboy, Marc
Sent: Tuesday, April 20, 2010 6:43 AM
To: Warburton, Karen
Subject: RE: K100349 AI

Karen:
I do not have edits, but I did have this single deficiency in my review:
(b)(4)

'arc Robboy, OD
.arc Robboy/ Optometrist/ Clinical Reviewer

34

US Food & Drug Administration/ Center for Devices and Radiological Health
Division of Ophthalmic, Neurological and ENT Devices
raocular, Cornea and Neuromaterials Branch

hite Oak Building 66, Room 2256
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 301.796.6860
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From: Warburton, Karen
Sent: Monday, April 19, 2010 8:20 PM
To: Kiang, Tina; Shih, Ming; Robboy, Marc
Subject: K100349 AI

Here are the AI questions that I've drafted to be relayed to the sponsor (email). Please let me know if you have edits. Thanks.

Additional information is necessary in order to complete review of this 510(k). The following request for ormation should be relayed to the sponsor.

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Warburton, Karen

om: Shih, Ming
nt: Monday, April 19, 2010 8:57 PM
: Warburton, Karen
Subject: RE: K100349 AI

Karen,

It looks ok to me.

Ming-chuen Shih, M.S.
Intraocular, Corneal & Neuromaterials Devices Branch
Division of Ophthalmic, Neurological and ENT Devices
Office of Device Evaluation
Center for Devices and Radiologic Health
Food and Drug Administration
Phone: 301-796-6860
FAX: 301-847-8126
Email: ming-chuen.shih@fda.hhs.gov
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mail or telephone.

From: Warburton, Karen
Sent: Monday, April 19, 2010 8:20 PM
To: Kiang, Tina; Shih, Ming; Robboy, Marc
Subject: K100349 AI

(b)(4)

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(b)(4)

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Memorandum

Date: March 30, 2010

From: Ming-chuen Shih, Chemist, ICNB/DONED M.S.

Subject: Chemistry Review for K100349 from Johnson & Johnson Vision Care, Inc
Device Trade Name: VISTAKON® (narafileon B) Contact Lens

To: Records through Karen Warburton, Team Leader

Introduction

Johnson & Johnson Vision Care, Inc. (the Company), submits this premarket notification for the VISTAKON® (narafilcon B) Contact Lens Visibility Tinted, with UV Blocker.

Device Description

- The VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV blocker is available as a spherical lens, a multifocal lens, a toric lens and a multifocal-toric lens.
- The lenses are made of a silicone hydrogel material containing an internal wetting agent.
- The VISTAKON® (narafilcon B) Contact Lens may be 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® (narafilcon 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% narafilcon B and 48% water by weight when hydrated and stored in the buffered saline solution.

Indications for Use

The VISTAKON® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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.

Predicate devices

Material
VISTAKON® (narafilcon A) Contact Lens – K073485
(FDA Group I; low water, nonionic polymer)
Indication, Wear Schedule
VISTAKON® (etafilcon A) Contact Lenses – K962804
(Daily wear, single use)(*Reviewer's note: This is a Group IV lens: high water, ionic polymer)*

Note: The VISTAKON® (narafilcon A) Contact Lens has not been marketed in the United States.

Review

Lens Material

- The lens material, narafilcon B, is a copolymer of 2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester polymer with Poly[oxy(dimethylsilylene)], α-(butyldimethylsilyl)-ω-[[[3-[2- hydroxy-3-[(2-methyl-1-oxo-2 propenyl)oxy]propoxy]propyl]dimethylsilyl]oxy]- and 2- propenamide, N,N-dimethyl and 2-pyrrolidinone, 1- ethenyl-, homopolymer and 2-Propenoic acid, 2-methyl-, oxybis(2,1- ethanediyloxy-2,1-ethanediyl) ester. *
- The VISTAKON® (narafilcon 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 composition of the lens is 52% narafilcon B and 48% water by weight when hydrated and stored in the buffered saline solution

The following statement is from the USAN Council for narafilcon B

N10/12

January 27, 2010

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

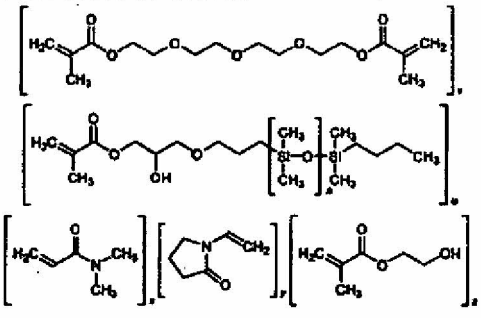
USAN (xx-48)	NARAFILCON B
PRONUNCIATION	nar" a fil' kon
INGREDIENT FUNCTION	contact lens material (hydrophilic)

CHEMICAL NAME

1. 2-Propenoic acid, 2-methyl-, 1,1'-[oxybis(2,1-ethanediyloxy-2,1-ethanediyl)] ester, polymer with α-(butyldimethylsilyl)-ω-[[[3-[2-hydroxy-3-[(2-methyl-1-oxo-2-propen-1-yl)oxy]propoxy]propyl]dimethylsilyl]oxy]poly[oxy(dimethylsilylene)], *N*,*N*-dimethyl-2-propenamide, 1-ethenyl-2-pyrrolidinone and 2-hydroxyethyl 2-methyl-2-propenoate

2. 2,2'-[oxybis(ethyleneoxy)]diethyl bis(2-methylprop-2-enoate) polymer with α-(butyldimethylsilyl)-ω-(3-{(2*RS*)-2-hydroxy-3-[(2-methylprop-2-enoyl)oxy]propoxy}propyl)poly[oxy(dimethylsilylene)], *N*,*N*-dimethylprop-2-enamide, 1-ethenylpyrrolidin-2-one and 2-hydroxyethyl 2-methylprop-2-enoate

STRUCTURAL FORMULA



MOLECULAR FORMULA	$[C_{16}H_{32}O_4Si[C_2H_6OSi]_n]_w \cdot [C_{16}H_{26}O_7]_v \cdot [C_6H_{10}O_3]_z \cdot [C_6H_9NO]_y \cdot [C_5H_9NO]_x$
CODE DESIGNATION	n/a
MANUFACTURER	Johnson & Johnson Vision Care, Inc.
WATER CONTENT (at ambient temperature (23±2°C)	48%
OXYGEN PERMEABILITY at 35°C (Dk Value)	55×10^{-11} (cm^2/s)(mL O_2/mL•mmHg) (edge & boundary corrected)
CAS REGISTRY NUMBER	909294-16-2
HMB	

Chemical Composition

The chemical composition for the narafilcon B contact lens material is listed below with reference to mole and weight percentages. The

(b)(4)

The ingredients for this lens include several monomers. The Company also indicates that

(b)(4)

42

Lens Properties (as described in the labeling (p. G-7))

- Specific Gravity: 1.07
- Refractive Index: 1.41
- Light Transmittance: 85% minimum
- Surface Character : Hydrophilic
- Water Content: 48%
- Oxygen Permeability:

VALUE	METHOD
55 x 10^{-11} (cm2/sec) (ml O_2/ml x mm Hg) at 35°C	Polarographic edge and boundary corrected

*For light transmittance, the Company should provide light transmittances for the visible light and UV A and UV B ranges in the labeling***.*

Lens Parameters (as described in the labeling (p. G-7))

The VISTAKON® (narafilcon B) Contact Lenses are a hemispherical and/or hemitoric shell available within the following dimensions:

Diameter Range:		12.0mm to 15.0mm
Center Thickness:		Low minus lens – (0.085mm) Plus lens – varies with power (e.g., +3.00D: 0.170mm)
Base Curve Range:		7.80mm to 10.00mm
Power Range:		
Spherical Power:	Daily Wear	-20.00D to +20.00D
Multifocal ADD Powers:		+0.25D to +4.00D
Multifocal-Toric ADD Powers:		+0.25D to +4.00D
Cylinder Power:		-0.25D to -10.00D
Axis:		2.5 ° to 180 °

According to the Company's note (p.77), the tolerances of the lens parameters described on page 77 are consistent with (b)(4) to the extent discussed in the Standards Data Summary Report provided in Attachment I. They are the same as those identified in K073485 (p.77).

Specifications for contact lens physicochemical properties

The Company summarized the lens property specification ranges for the VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV Blocker in the table below:

Property	Specification
Water Content, %	(b)(4)
Refractive Index @ 20°C	
*Dk, edge corrected	
Color	
Light Transmittance @ 380 - 780 nm, %	
Light Transmittance @ 316 - 380 nm, %	
Light Transmittance @ 280 - 315 nm, %	
Tensile Strength, psi	
Elongation, %	
Modulus, psi	
Toughness, in lb/in^3	
Dynamic Contact Angle (°), (DCA)	

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

(b)(4)

Engineering Drawings

The engineering drawings for the spherical and aspherical single vision lenses, multifocal lens, toric lens and multifocal – toric lens are provided in Attachment A. The Company noted that "As noted in K073485, the substantial equivalence of the multifocal optical theory has been previously cleared by FDA in

(b)(4)

Manufacturing/control (pp. 80-81)

(b)(4)

(b)(4)

All lenses are manufactured in full compliance with the 21 CFR 820 Quality System Regulations according to the Company.

The Company noted that the manufacturing process described above is the same as currently identified in K073485, with the exception for chemical composition that is identified in this notification.

(b)(4)

(b)(4) *However, the Company indicated that all lenses are manufactured in full compliance with the 21 CFR 820 Quality System Regulations (p.80.) which requires manufacturing processes validation.*

Visibility Tinting Process:

(b)(4)

Packaging Materials and Methods:

The VISTAKON® (narafilcon B) Contact Lens is packaged in buffered saline solution with methyl ether cellulose solution in a (b)(4) blister (b)(4) d (b)(4) lidstock.

The Company noted that the packaging system described above is used by JJVCI for

all marketed contact lens products. Reference (b)(4)
(b)(4)

(b)(4)

Manufacturing Flow Diagram:

A manufacturing flow diagram is provided in **Attachment B**. (p.B-2)

The following two notes are included in the manufacturing flow diagram.

1. (b)(4)
2.

The Company should:

1. (b)(4)
2.

Lens Inspection:

(b)(4)

Substantial Equivalence

Predicate Device(s)

Material:
VISTAKON® (narafilcon A) Contact Lens – K073485
(FDA Group I; low water, nonionic polymer (*Daily wear, single use*))

Indication, Wear Schedule:
VISTAKON® (etafilcon A) Contact Lenses– K962804
(*(Group IV; high water, ionic polymer)* Daily wear, single use)

The following comparison tables are provided for material comparison, parameter comparison, and indication for use comparison (pp.86, 87).

Material Comparison		
	Predicate Device	**Subject Device**
Product Name	VISTAKON® (narafilcon A) Contact Lens	VISTAKON® (narafilcon B) Contact Lens
Material USAN Name	narafilcon A	narafilcon 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® (narafilcon A) Contact Lens – K073485		**Subject Device VISTAKON® (narafilcon 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

*Dk units: 10^{-11} (cm^2/sec)(ml O_2/ml x mmHg)

Indications for Use Comparison			
	Predicate Devices		**Subject Device**
	VISTAKON® (narafilcon A) Contact Lens **K073485**	1-DAY ACUVUE® Brand (etafilcon A) Contact Lens **K962804**	VISTAKON® (narafilcon B) Contact Lens **Unknown**
Spherical - Intended Use	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.	Indicated for daily wear single use for the correction of refractive ametropia (myopia hyperopia, and presbyopia) in aphakic or non-aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.	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 - Intended Use	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.	Indicated for daily wear single use for the correction of distance and near vision in presbyopic, aphakic or non-aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less.	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 - Intended Use	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.	Indicated for daily wear single use for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D or less of astigmatism	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-Intended Use	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.	Indicated for daily wear single use for the correction of distance and near vision in presbyopic aphakic or non-aphakic persons with non-diseased eyes who may have 10.00D of astigmatism or less.	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.

(b)(4)

Property	Specification
Water Content, %	(b)(4)
Refractive Index @ 20°C	
*Dk, edge corrected	
Color	
Light Transmittance @ 380 - 780 nm, %	
Light Transmittance @ 316 - 380 nm, %	
Light Transmittance @ 280 - 315 nm, %	
Tensile Strength, psi	
Elongation, %	
Modulus, psi	
Toughness, in lb/in^3	
Dynamic Contact Angle (°), (DCA)	

*Dk units: 10^{-11}(cm^2/sec)(ml O_2/ml x mmHg)

Property	Predicate Device, measured (SD)	Predicate Device, labeled	Subject Device, measured (SD)	Subject Device, labeled
Water Content, %	47 n=9 (0.4)	46	48 n=9 (0.1)	48
Refractive Index @ 20°C	1.40 n=6 (0.00)	1.41	1.41 n=6 (0.00)	1.41
Dk*, edge corrected	96 n=4 (NA)	100	52 n=4 (NA)	55
Color	Blue n=1	Blue	Blue n=1	Blue
Light Transmittance @ 380-780nm, %	97.29 n=5 (0.30)	94 +/- 5%	96.1 n=5 (0.9)	94 +/- 5%
Light Transmittance @ 316-380nm, %	3.48 n=5 (0.21)	<10 %	3.7 n=5 (0.5)	<10 %
Light Transmittance @ 280-315nm, %	0.01 n=5 (0.00)	<1 %	0.1 n=5 (0.0)	<1 %
Tensile Strength, psi	94 n=12 (16)	NA	87 n=12 (31)	NA
Elongation, %	217 n=12 (53)	NA	190 n=12 (75)	NA
Modulus, psi	104 n=12 (10)	NA	109 n=12 (10)	NA
Toughness, (in lb/in^3)	116 n=12 (44)	NA	99 n=12 (69)	NA
Dynamic Contact Angle, °	57 n=5 (4)	NA	54 n=5 (10)	NA
Base Curve, mm	8.53 n=10 (0.04)	8.5	8.49 n=8 (0.03)	8.5
Diameter, mm	14.26 n=10 (0.03)	14.2	14.19 n=8 (0.02)	14.2
Power, diopters	-0.92 n=10 (0.04)	-1.00	-0.98 n=8 (0.03)	-1.00
Center Thickness, mm	0.085 n=10 (0.007)	NA	0.086 n=8 (0.004)	NA

*Dk units: 10^{-11}(cm^2/sec)(ml O_2/ml x mmHg)

Modifications of a contact lens material may have a significant impact on the performance characteristics of the approved/cleared lens. Therefore, a company should

provide data in its 510(k) sufficient to adequately characterize the modified lens in terms of its physical/chemical/optical characteristics when compared to the previously approved/cleared lens.

*The Company should provide statistical analyses of the oxygen permeability, dynamic contact angle, tensile strength, elongation, modulus, and toughness testing data to determine the equivalence of these properties for the VISTAKON® (narafilcon A) and VISTAKON® (narafilcon B) lens materials. The Company should refer to the FDA May 12, 1994 Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses (p.21) for sample size determination. If the company are unable to determine the lens material equivalency based on bench test, it should conduct clinical test for these two lenses to support its claim that VISTAKON® (narafilcon A) Contact Lens is the predicate for VISTAKON® (narafilcon B) Contact Lens based on lens material. Otherwise, the Company should remove this claim. Please refer to page 49 of the guidance mentioned above for guidance.****

Packaging

It indicates in Section 14 that the VISTAKON® (narafilcon B) Contact Lens is packaged in a (b)(4) blister sealed to a (b)(4) overlay. This is the same primary packaging system used to maintain the sterility of all VISTAKON® marketed contact lens products. Reference is made to K073485.

It states in Attachment C- Shelf Life Protocol that the packaging system consists of the following:

1. (b)(4)
2.
3.

(b)(4)

According to the How Supplied section of the labeling (p.G-25), the lens packing solution is a buffered saline solution with methyl ether cellulose. The Company should (b)(4) *this 510(k). Since the interaction between the lens material and the packing solution may vary from lens to lens.* (b)(4)

(b)(4)

Shelf life

Shelf life stability testing for the VISTAKON® (narafilcon B) Contact Lens was generated according to the protocol provided in **Attachment C**. The parameters

(b)(4)

Leachability

The table below provides representative leachable monomer and additive data for the VISTAKON® (narafilcon B) Contact Lens in comparison to the VISTAKON® (narafilcon A) Contact Lens. The extractions were performed according to the methods specified in the table (b)(4)

(b)(4)

Material	Lens Wt. µg/g		Method Overview
	narafilcon B	narafilcon A	
(b)(4)			

The reported leachables for VISTAKON® (narafilcon A) Contact Lens are identical to those reported in K073485 according to the Chemistry Review for K073485. The main differences in chemical compositions for narafilcon A and narafilcon B material are the

(b)(4)

(b)(4)

Recommendation

The information provided in this 510(k) is inadequate to support a substantially equivalent determination for the VISTAKON® (narafilcon B) Contact Lens from a chemistry perspective. The following issues should be conveyed to the Company for resolution.

Formulation

1. (b)(4)

52

Specifications for contact lens properties

2. (b)(4)

Packaging

3. It states in Attachment C- Shelf Life Protocol that the packaging system consists of the following:

4. (b)(4)

(b)(4)

Manufacturing

5. (b)(4)

Substantial equivalence

6. (b)(4)

Property	Specification
Water Content, %	(b)(4)
Refractive Index @ 20°C	
*Dk, edge corrected	
Color	
Light Transmittance @ 380 - 780 nm, %	
Light Transmittance @ 316 - 380 nm, %	
Light Transmittance @ 280 - 315 nm, %	
Tensile Strength, psi	
Elongation, %	
Modulus, psi	
Toughness, in lb/in^3	
Dynamic Contact Angle (°), (DCA)	

*Dk units: 10^{-11}(cm^2/sec)(ml O_2/ml x mmHg)

Property	Predicate Device, measured (SD)	Predicate Device, labeled	Subject Device, measured (SD)	Subject Device, labeled
Water Content, %	47 n=9 (0.4)	46	48 n=9 (0.1)	48
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Dk*, edge corrected	96 n=4 (NA)	100	52 n=4 (NA)	55
Color	Blue n=1	Blue	Blue n=1	Blue
Light Transmittance @ 380-780nm, %	97.29 n=5 (0.30)	94 +/- 5%	96.1 n=5 (0.9)	94 +/- 5%
Light Transmittance @ 316-380nm, %	3.48 n=5 (0.21)	<10 %	3.7 n=5 (0.5)	<10 %
Light Transmittance @ 280-315nm, %	0.01 n=5 (0.00)	<1 %	0.1 n=5 (0.0)	<1 %
Tensile Strength, psi	94 n=12 (16)	NA	87 n=12 (31)	NA
Elongation, %	217 n=12 (53)	NA	190 n=12 (75)	NA
Modulus, psi	104 n=12 (10)	NA	109 n=12 (10)	NA
Toughness, (in lb/in^3)	116 n=12 (44)	NA	99 n=12 (69)	NA
Dynamic Contact Angle, °	57 n=5 (4)	NA	54 n=5 (10)	NA
Base Curve, mm	8.53 n=10 (0.04)	8.5	8.49 n=8 (0.03)	8.5
Diameter, mm	14.26 n=10 (0.03)	14.2	14.19 n=8 (0.02)	14.2
Power, diopters	-0.92 n=10 (0.04)	-1.00	-0.98 n=8 (0.03)	-1.00
Center Thickness, mm	0.085 n=10 (0.007)	NA	0.086 n=8 (0.004)	NA

*Dk units: 10^{-11}(cm^2/sec)(ml O_2/ml x mmHg)

In your substantial equivalence discussion (p. 85- 87, Section 12), you did not

(b)(4)

(b)(4)

Shelf life

7. (b)(4)

Labeling

8. (b)(4)

*** Deficiency marker

File name: k100349 Chemistry Review.doc

57

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: April 15, 2010

From: Susanna Jones, Toxicologist, ODE/DONED/ICNB, WO66-2468

Subject: Biocompatibility Review of K100349
Johnson & Johnson Vision Care, Inc.
VISTAKON® (narafilcon B) Contact Lens Visibility Tinted, with UV Blocker

To: Record, K100349

Indications for Use:

The VISTAKON® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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.

Submitted: The sponsor is seeking clearance to market the VISTAKON® (narafilcon B) Contact Lenses. The lenses are made from a modified lens material, narafilcon B. The lens material is a silicone hydrogel material containing an internal wetting agent, and 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.

Substantial Equivalence: The sponsor is claiming as the predicate device the narafilcon A contact lens (K073485). The following table compares the chemical composition of the narafilcon A and narafilcon B materials:

Material	Function	Purity (%)	K100349		K073485	
			Wt (%)	Mole (%)	Wt (%)	Mole (%)
(b)(4)						

Comment: The chemical composition of narafilcon B is essentially the same as the predicate, narafilcon A, except for the proportions of the three monomers.

Biocompatibility Testing: Biocompatibility testing was conducted for the VISTAKON® (narafilcon A) Contact Lens (reference K073485 cleared on March 3, 2008). The sponsor asserts

(b)(4)

In addition, the sponsor conducted the following verification tests to demonstrate that the lens (narafilcon B) is non-irritant and non-toxic:

- (b)(4)
-

(b)(4)

Comments:

- The test results provide reasonable assurance that the device and its packaging materials are biocompatible.
- (b)(4)

Conclusion/Recommendation: From a biocompatibility perspective, this submission can be found substantially equivalent.

K100349
510(k) Clinical Review

Date: March 24, 2010

From: Marc Robboy Marc Robboy

To: The Record

Through: Karen Warburton, Team Leader

Subject: K100349 Premarket Notification

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

Contact:
Catherine C. Dillon
Project Leader I
Regulatory Affairs
Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Suite 100
Jacksonville, FL 32256
904-443-3180
cdillon9@its.jnj.com

Background:
The purpose of this submission is to provide notification of intent to market a new daily wear soft contact lens, VISTAKON® (narafilcon B) Contact Lens Clear and Visibility Tinted, with UV blocker. The VISTAKON® (narafilcon 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® (narafilcon 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 lens is supplied in a sterile state, packaged in a buffered saline solution with methyl ether cellulose. The composition of the lens is 52% narafilcon B and 48% water by weight when hydrated and stored in the buffered saline solution. The predicate devices referenced include VISTAKON® (narafilcon A) Contact Lens – K073485, and VISTAKON® (etafilcon A) Contact Lenses – K962804.

Indications for Use:
The VISTAKON® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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.

Clinical Testing:
In order to support substantial equivalence, a one-month clinical study was undertaken to evaluate the safety and efficacy of the VISTAKON® (narafilcon B) Contact Lens for single use daily wear only.

The clinical report is presented in attachment H. The IRB-approved protocol is included as an appendix to the report. The (b)(4) study investigators are listed on page H-7. The study was conducted under the approval of the (b)(4)

Study Design:
The (b) -investigator, 1-month daily disposable clinical study was a (b)(4) (b)(4) design.

The objective of this study was to evaluate the single use daily wear clinical performance of the VISTAKON® Investigational (narafilcon) contact lens compared to the *1-DAY ACUVUE® Brand Contact Lenses*. The sponsor intended to show the VISTAKON® Investigational (narafilcon) contact lens is clinically substantially equivalent to the control lens, with respect to Slit Lamp Findings, Symptoms, Visual Acuity, and Average Wear Time. (b)(4) (b)(4)

The performance parameters that were monitored and evaluated included adverse events, keratometry changes, reasons for discontinuation, and number and reasons for unscheduled lens replacements.

Study Endpoints

(b)(4)

Comment:
The sample size and Test: Control ratio satisfy the recommendations in the FDA Guidance.

Enrollment Criteria:
Inclusion and Exclusion criteria are described on pages H-21 and H-22.

Comment:
The criteria are similar to those typically used in studies like this.

Data Analysis:
The following tests were performed using data collected from all successfully completed subjects at each scheduled follow-up visit.

(b)(4)

Analysis Population
Analyses were preformed for the Per Protocol (PP) populations, which included all subjects who successfully completed the clinical study.

Protocol Deviations
There were subjects involved in protocol deviations during the study; involved subjects taking medications which would have deemed them as ineligible. One deviation

(b)(4)

(b)(4)

(b)(4)

Comment:
These deviations are considered minor.

Subject Disposition:

(b)(4)

(b)(4)

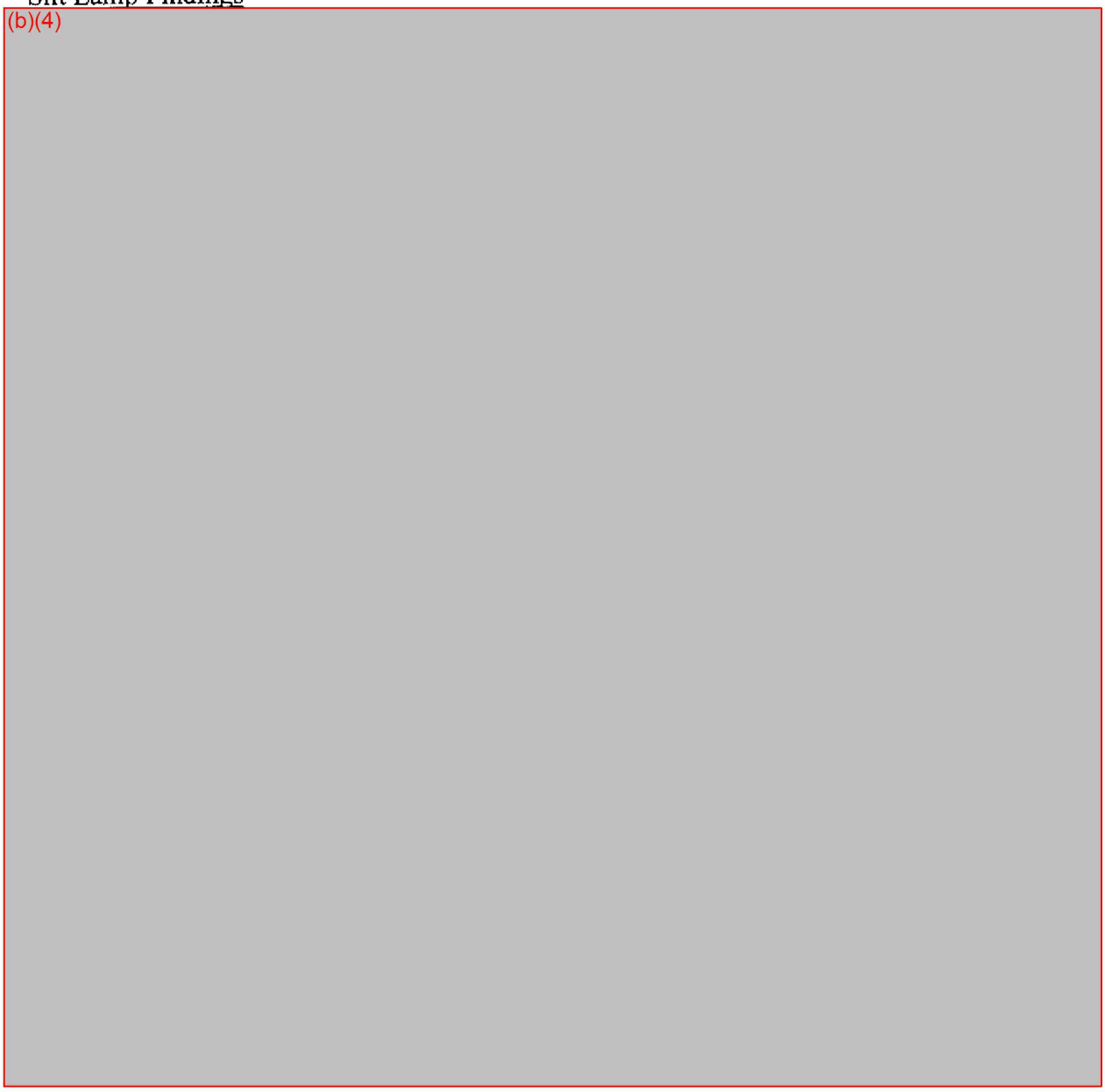
Comment:
This distribution of previous vs new wearers is a good mix.

STUDY RESULTS (Pages H-34 to H-48)

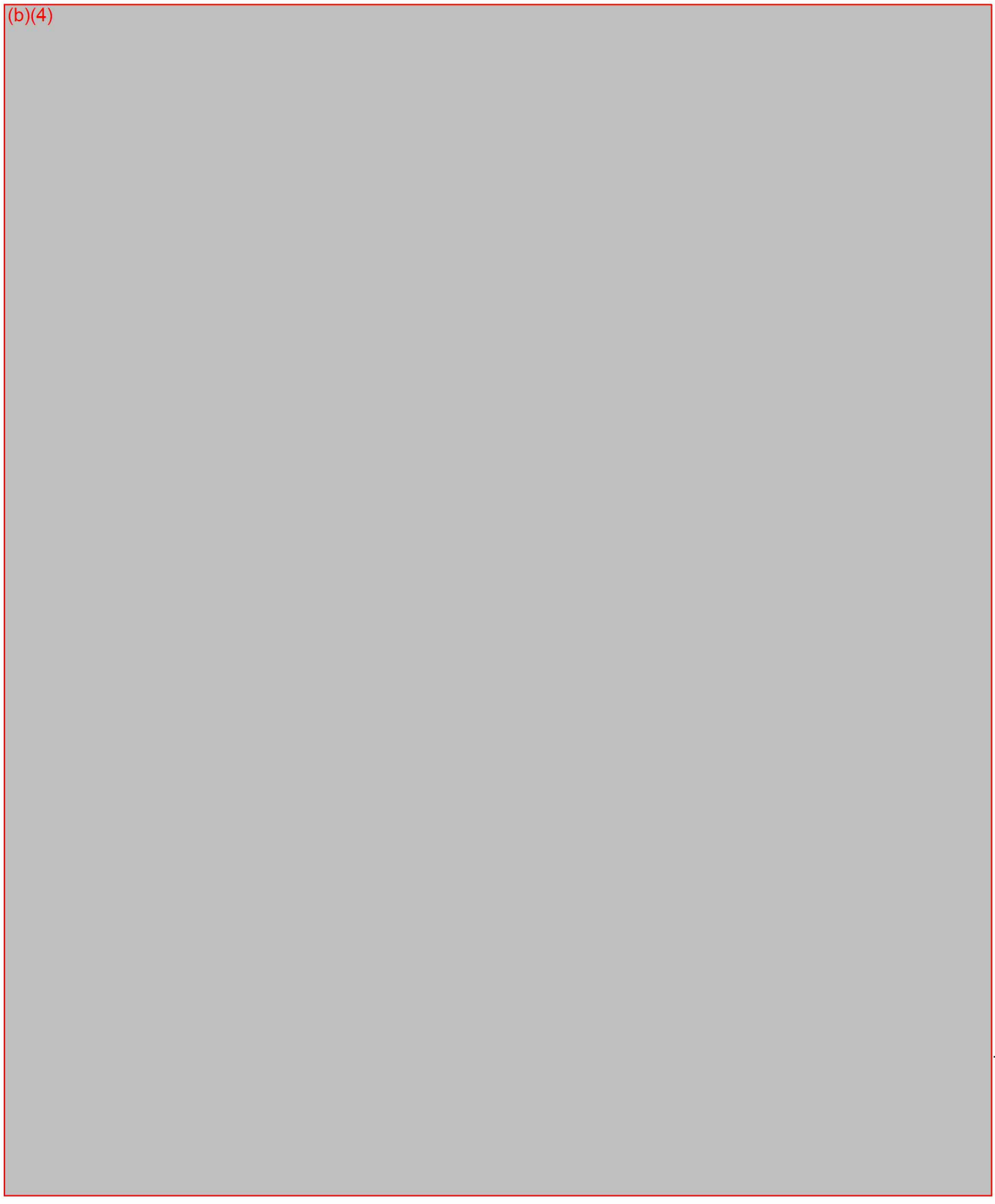
Safety
Adverse Events:
No adverse events (serious or significant) were reported for the Test or the Control groups.

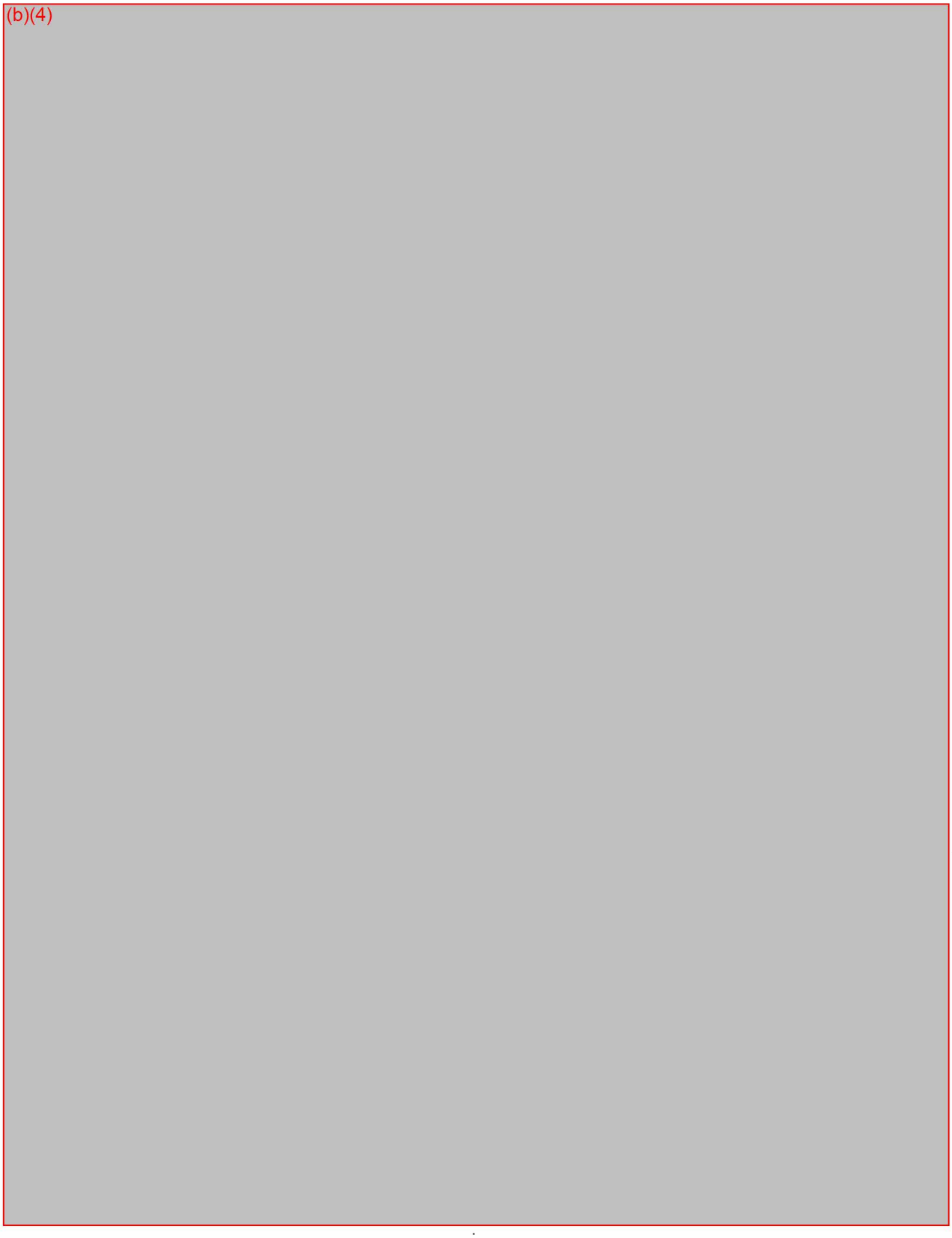
Slit Lamp Findings

(b)(4)

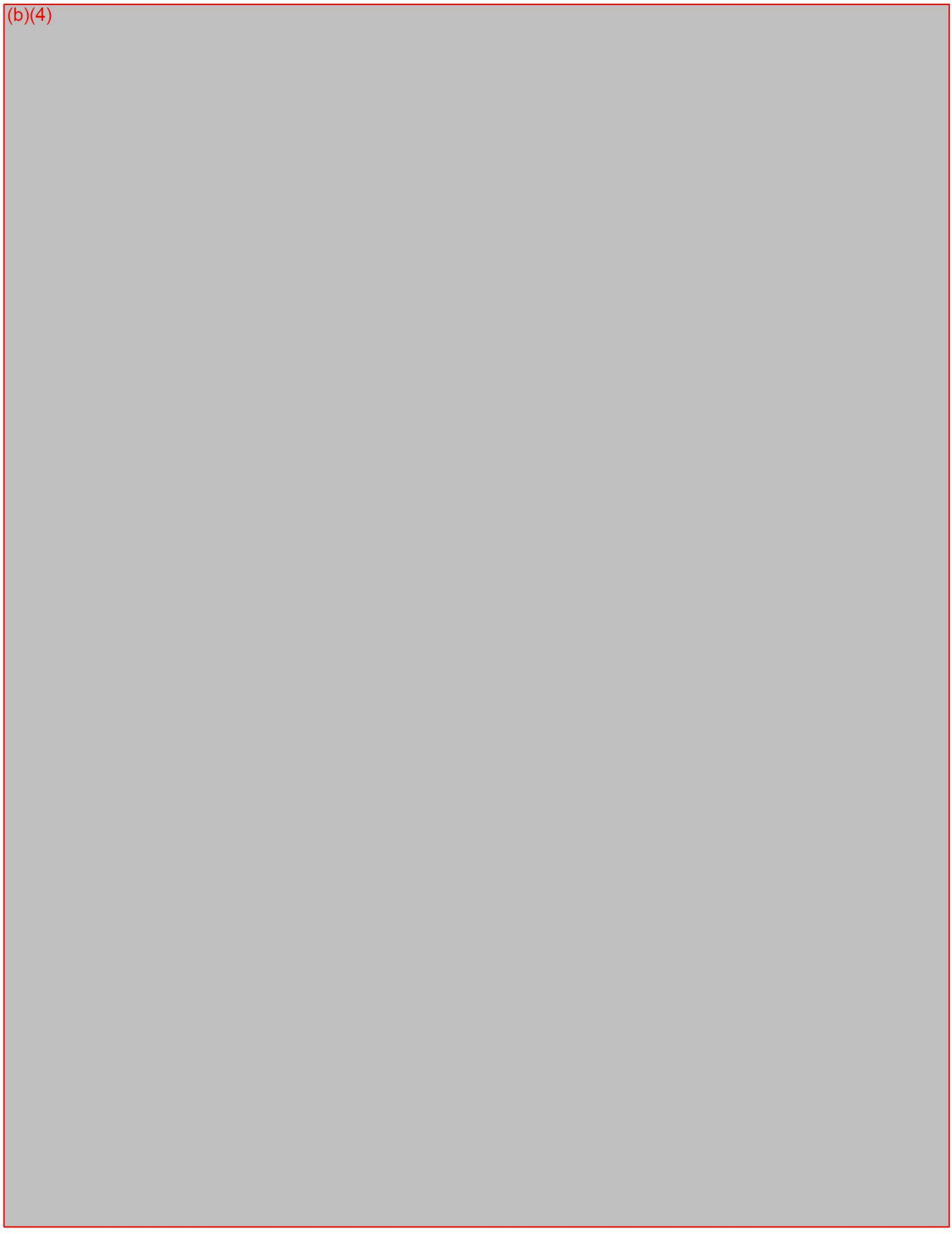


(b)(4)




(b)(4)

(b)(4)



Conclusion/ Recommendations:
As presented, this application does not provide sufficient information regarding the device under review to render a decision of substantial equivalence. The sponsor should address the following deficiency:

(b)(4)

COVER SHEET MEMORANDUM

Office of Device Evaluation &
Office of In Vitro Diagnostics

From: Reviewer Name Karen Warburton

Subject: 510(k) Number K100349

To: The Record

Please list CTS decision code TH (email)

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

7/2[redacted]

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		

Regulation Number 866.5925 **Class*** II **Product Code** LPL

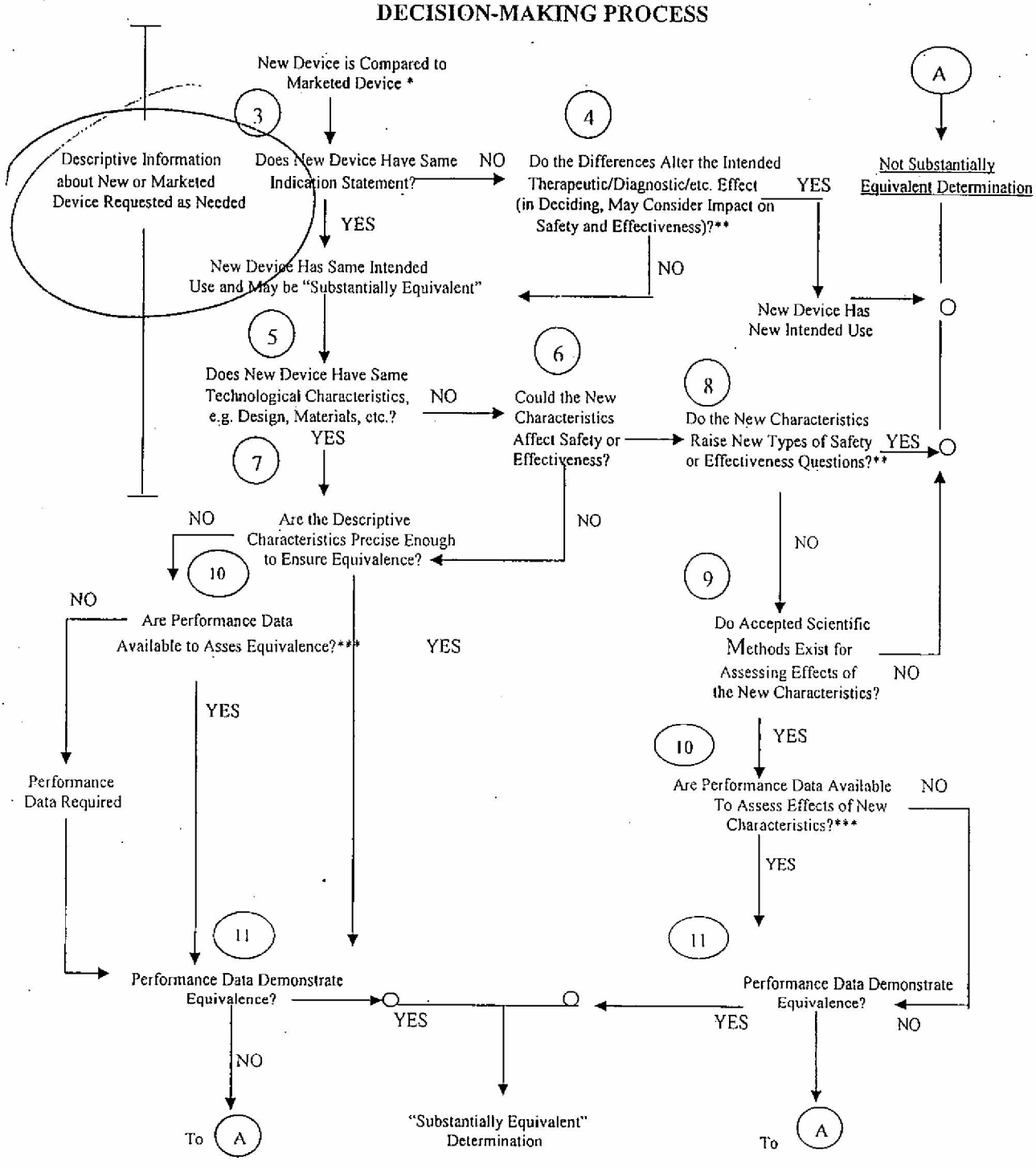
(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____ (Branch Chief) 4 ICNB (Branch Code) 4/26/10 (Date)

Final Review: _____ (Division Director) _____ (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Warburton, Karen

From: Warburton, Karen
Sent: Monday, April 26, 2010 2:40 PM
To: 'cdillon9@its.jnj.com'; 'jzimovan@its.jnj.com'
Cc: Kiang, Tina
Subject: K100349 Additional information request

Re: K100349
Trade Name: Acuvue® TruEye™ (narafilcon B) Contact Lens
Dated: February 8, 2010
Received: February 12, 2010

Dear Ms. Dillon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information:

1. (b)(4)
2.
3.
4.
5.
6.
7.

77

(b)(4)

8.

9.

10.

The deficiencies identified above 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 (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).
If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at **http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf**

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 additional information 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.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609

77

10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

'ease note that the 510(k) will be placed on hold pending your response to this request for additional
.ormation.

Karen

Karen Warburton, MT, MHS
Microbiologist
Intraocular, Corneal, and Neuromaterials Branch (ICNB)
Division of Ophthalmic, Neurological and ENT Devices
Office of Device Evaluation
Center for Devices and Radiological Health

(301) 796-5620 ***NEW number***
karen.warburton@fda.hhs.gov

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Date: April 19, 2010

From: Karen Warburton, Microbiologist and Team leader Karen Warburton

Subject: K100349 Vistakon (narafilcon B) Contact Lens Visibility Tinted with UV Blocker– Team leader and Microbiology review

To: The Record

Through: Chief, Intraocular, Corneal and Neuromaterials Branch
Tina Kiang, Ph.D. 4/26/10

Indications for use:

The VISTAKON® (narafilcon 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®(narafilcon 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®(narafilcon 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® (narafilcon 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® (narafilcon 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.

Reviewer's comments The indications for the multifocal and multifocal toric lenses should include the ADD power ranges.

Device Description

The lens material is narafilcon B, a silicone hydrogel material that includes a visibility tint (Reactive Blue Dye #4) and a UV absorber (benzotriazole). The lens is 48% water with a Dk of 55±20%. The lens is molded and the sponsor states that the manufacturing process is the same as that for the narafilcon A lens, with the exception of the proportions of monomers in the formulation. The lens is packaged in a buffered saline solution containing methyl ether cellulose in a polypropylene blister pack with laminated aluminum foil lidstock. The same packaging system is used for all currently marketed Vistakon lenses.

Microbiology

(b)(4)

Shelf-life

(b)(4)

Reviewer's comments *The shelf-life protocol is acceptable. The sponsor is correct—no additional shelf-life sterility testing is necessary.*

Labeling

Proposed labeling (primary, secondary, package insert and fitting and management guide, and patient instruction guide) was provided.

Reviewer's comments *The indications for use should be modified as noted above.*

Consulting reviews

A clinical review was performed by Marc Robboy, O.D. who identified one deficiency that should be relayed to the sponsor.

A chemistry review was performed by Ming Shih, who identifies deficiencies that should be relayed to the sponsor.

A toxicology review was performed by Susanna Jones, who indicates that from a biocompatibility perspective the submission can be found to be substantially equivalent.

Team leader's comments *This lens is a new silicone hydrogel lens. The sponsor provided no*

(b)(4)

Conclusion/recommendation

Additional information is necessary in order to complete review of this 510(k). The following request for information should be relayed to the sponsor.

1. (b)(4)
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Date: April 21, 2010

From: Karen Warburton, Microbiologist and Team leader Karen Warburton

Subject: K100349 Vistakon (narafilcon B) Contact Lens Visibility Tinted with UV Blocker– Team leader and Microbiology review--Addendum

To: The Record

Through: Chief, Intraocular, Corneal and Neuromaterials Branch
Tina Kiang, Ph.D. 4/26/10

Based on feedback from Drs. Kiang and Robboy, the additional information questions have been modified as follows.

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(b)(4)

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Warburton, Karen

om: Kiang, Tina
nt: Tuesday, April 20, 2010 4:08 PM
.o: Warburton, Karen
Cc: Shih, Ming; Robboy, Marc
Subject: RE: K100349 AI

Importance: High

Please see edits. In addition, there appears to be deficiencies in both Ming's and Marc's reviews that were not included in this email. However, you did not explain why these deficiencies are not being relayed in your review, nor that the reviewers provided concurrence on not relaying these deficiencies. You also did not appear to address your own comment regarding (b)(4) in your review. Please revise your review and add the additional deficiencies, or provide comment as to why they will not be included. Please provide a revised review and draft email for me to review.

Tina

From: Warburton, Karen
Sent: Monday, April 19, 2010 8:20 PM
To: Kiang, Tina; Shih, Ming; Robboy, Marc
Subject: K100349 AI

Here are the AI questions that I've drafted to be relayed to the sponsor (email). Please let me know if you have edits. Thanks.

Additional information is necessary in order to complete review of this 510(k). The following request for formation should be relayed to the sponsor.

1. (b)(4)
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36

7. (b)(4)

8.

87

Warburton, Karen

From: Robboy, Marc
Sent: Tuesday, April 20, 2010 11:08 AM
To: Warburton, Karen
Subject: RE: K100349 AI

Hi Karen:
I reviewed some 510(k)s and you are correct that some IFU contain ranges fro multifocals, although some do not. However, some of the Torics do also:
Toric - Biomedics 55 (ocufilcon D) TORIC Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and nonaphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters **and astigmatic corrections from -0.25 to -10.00 diopters.**

So to be consistent if we are asking for a Multifocal range we should also request a Toric range, don't you agree?
Marc

Marc Robboy, OD
Marc Robboy/ Optometrist/ Clinical Reviewer
US Food & Drug Administration/ Center for Devices and Radiological Health
Division of Ophthalmic, Neurological and ENT Devices
Intraocular, Cornea and Neuromaterials Branch

White Oak Building 66, Room 2256
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 301.796.6860
Fax: 301.847.8126
Email: marc.robboy@fda.hhs.gov

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From: Robboy, Marc
Sent: Tuesday, April 20, 2010 6:43 AM
To: Warburton, Karen
Subject: RE: K100349 AI

Karen:
I do not have edits, but I did have this single deficiency in my review:
(b)(4)

Marc

Marc Robboy, OD
Marc Robboy/ Optometrist/ Clinical Reviewer

88

US Food & Drug Administration/ Center for Devices and Radiological Health
Division of Ophthalmic, Neurological and ENT Devices
Intraocular, Cornea and Neuromaterials Branch

hite Oak Building 66, Room 2256
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Silver Spring, MD 20993
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From: Warburton, Karen
Sent: Monday, April 19, 2010 8:20 PM
To: Kiang, Tina; Shih, Ming; Robboy, Marc
Subject: K100349 AI

Here are the AI questions that I've drafted to be relayed to the sponsor (email). Please let me know if you have edits. Thanks.

Additional information is necessary in order to complete review of this 510(k). The following request for information should be relayed to the sponsor.

1. (b)(4)
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6. (b)(4)

7.

Warburton, Karen

From: Shih, Ming
Sent: Monday, April 19, 2010 8:57 PM
To: Warburton, Karen
Subject: RE: K100349 AI

Karen,

It looks ok to me.

Ming-chuen Shih, M.S.
Intraocular, Corneal & Neuromaterials Devices Branch
Division of Ophthalmic, Neurological and ENT Devices
Office of Device Evaluation
Center for Devices and Radiologic Health
Food and Drug Administration
Phone: 301-796-6860
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Email: ming-chuen.shih@fda.hhs.gov
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From: Warburton, Karen
Sent: Monday, April 19, 2010 8:20 PM
To: Kiang, Tina; Shih, Ming; Robboy, Marc
Subject: K100349 AI

(b)(4)

(b)(4)

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92

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: March 30, 2010

From: Ming-chuen Shih, Chemist, ICNB/DONED M.S.

Subject: Chemistry Review for K100349 from Johnson & Johnson Vision Care, Inc
Device Trade Name: VISTAKON® (narafileon B) Contact Lens

To: Records through Karen Warburton, Team Leader

Introduction

Johnson & Johnson Vision Care, Inc. (the Company), submits this premarket notification for the VISTAKON® (narafilcon B) Contact Lens Visibility Tinted, with UV Blocker.

Device Description

- The VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV blocker is available as a spherical lens, a multifocal lens, a toric lens and a multifocal-toric lens.
- The lenses are made of a silicone hydrogel material containing an internal wetting agent.
- The VISTAKON® (narafilcon B) Contact Lens may be 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® (narafilcon 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% narafilcon B and 48% water by weight when hydrated and stored in the buffered saline solution.

Indications for Use

The VISTAKON® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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.

Predicate devices

Material
VISTAKON® (narafilcon A) Contact Lens – K073485
(FDA Group I; low water, nonionic polymer)
Indication, Wear Schedule
VISTAKON® (etafilcon A) Contact Lenses – K962804
(Daily wear, single use)(*Reviewer's note: This is a Group IV lens: high water, ionic polymer)*

Note: The VISTAKON® (narafilcon A) Contact Lens has not been marketed in the United States.

Review

Lens Material

- The lens material, narafilcon B, is a copolymer of 2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester polymer with Poly[oxy(dimethylsilylene)], **α**-(butyldimethylsilyl)-**ω**-[[[3-[2- hydroxy-3-[(2-methyl-1-oxo-2 propenyl)oxy]propoxy]propyl]dimethylsilyl]oxy]- and 2- propenamide, N,N-dimethyl and 2-pyrrolidinone, 1- ethenyl-, homopolymer and 2-Propenoic acid, 2-methyl-, oxybis(2,1- ethanediyloxy-2,1-ethanediyl) ester. *
- The VISTAKON® (narafilcon 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 composition of the lens is 52% narafilcon B and 48% water by weight when hydrated and stored in the buffered saline solution

The following statement is from the USAN Council for narafilcon B

N10/12

January 27, 2010

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

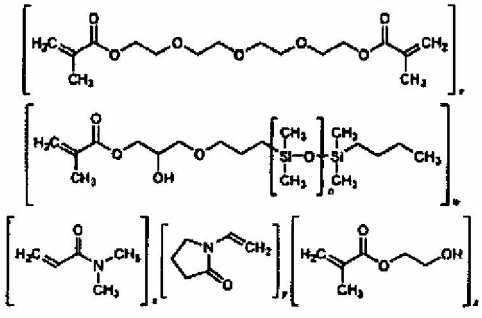
USAN (xx-48)	NARAFILCON B
PRONUNCIATION	nar" a fil' kon
INGREDIENT FUNCTION	contact lens material (hydrophilic)

CHEMICAL NAME

1. 2-Propenoic acid, 2-methyl-, 1,1'-[oxybis(2,1-ethanediyloxy-2,1-ethanediyl)] ester, polymer with α-(butyldimethylsilyl)-ω-[[[3-[2-hydroxy-3-[(2-methyl-1-oxo-2-propen-1-yl)oxy]propoxy]propyl]dimethylsilyl]oxy]poly[oxy(dimethylsilylene)], *N,N*-dimethyl-2-propenamide, 1-ethenyl-2-pyrrolidinone and 2-hydroxyethyl 2-methyl-2-propenoate

2. 2,2'-[oxybis(ethyleneoxy)]diethyl bis(2-methylprop-2-enoate) polymer with α-(butyldimethylsilyl)-ω-(3-[(2*RS*)-2-hydroxy-3-[(2-methylprop-2-enoyl)oxy]propoxy}propyl)poly[oxy(dimethylsilylene)], *N,N*-dimethylprop-2-enamide, 1-ethenylpyrrolidin-2-one and 2-hydroxyethyl 2-methylprop-2-enoate

STRUCTURAL FORMULA



MOLECULAR FORMULA	$[C_{16}H_{32}O_4Si[C_2H_6OSi]_n]_w \cdot [C_{16}H_{26}O_7]_v \cdot [C_8H_{10}O_3]_z \cdot [C_6H_9NO]_y \cdot [C_5H_9NO]_x$
CODE DESIGNATION	n/a
MANUFACTURER	Johnson & Johnson Vision Care, Inc.
WATER CONTENT (at ambient temperature (23±2°C)	48%
OXYGEN PERMEABILITY at 35°C (Dk Value)	55×10^{-11} (cm^2/s)(mL O_2/mL•mmHg) (edge & boundary corrected)
CAS REGISTRY NUMBER	909294-16-2
HMB	

Chemical Composition

The chemical composition for the narafilcon B contact lens material is listed below with reference to mole and weight percentages. The composition is fixed for narafilcon B (b)(4) of nominal.

Material	Function	Purity (%)	Wt (%)	Mole (%)
(b)(4)				

(b)(4)

Lens Properties (as described in the labeling (p. G-7))

- Specific Gravity: 1.07
- Refractive Index: 1.41
- Light Transmittance: 85% minimum
- Surface Character : Hydrophilic
- Water Content: 48%
- Oxygen Permeability:

VALUE	METHOD
55 x 10^{-11} (cm2/sec) (ml O_2/ml x mm Hg) at 35°C	Polarographic edge and boundary corrected

*For light transmittance, the Company should provide light transmittances for the visible light and UV A and UV B ranges in the labeling***.*

Lens Parameters (as described in the labeling (p. G-7))

The VISTAKON® (narafilcon B) Contact Lenses are a hemispherical and/or hemitoric shell available within the following dimensions:

Diameter Range:		12.0mm to 15.0mm
Center Thickness:		Low minus lens – (0.085mm) Plus lens – varies with power (e.g., +3.00D: 0.170mm)
Base Curve Range:		7.80mm to 10.00mm
Power Range:		
Spherical Power:	Daily Wear	-20.00D to +20.00D
Multifocal ADD Powers:		+0.25D to +4.00D
Multifocal-Toric ADD Powers:		+0.25D to +4.00D
Cylinder Power:		-0.25D to -10.00D
Axis:		2.5 ° to 180 °

According to the Company's note (p.77), the tolerances of the lens parameters described on page 77 are consistent (b)(4) the extent discussed in the Standards Data Summary Report provided in Attachment I. They are the same as those identified in K073485 (p.77).

Specifications for contact lens physicochemical properties

The Company summarized the lens property specification ranges for the VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV Blocker in the table below:

Property	Specification
Water Content, %	(b)(4)
Refractive Index @ 20°C	
*Dk, edge corrected	
Color	
Light Transmittance @ 380 - 780 nm, %	
Light Transmittance @ 316 - 380 nm, %	
Light Transmittance @ 280 - 315 nm, %	
Tensile Strength, psi	
Elongation, %	
Modulus, psi	
Toughness, in lb/in^3	
Dynamic Contact Angle (°), (DCA)	

*Dk units: 10^{-11}(cm^2/sec)(ml O_2/ml x mmHg)

(b)(4)

Engineering Drawings

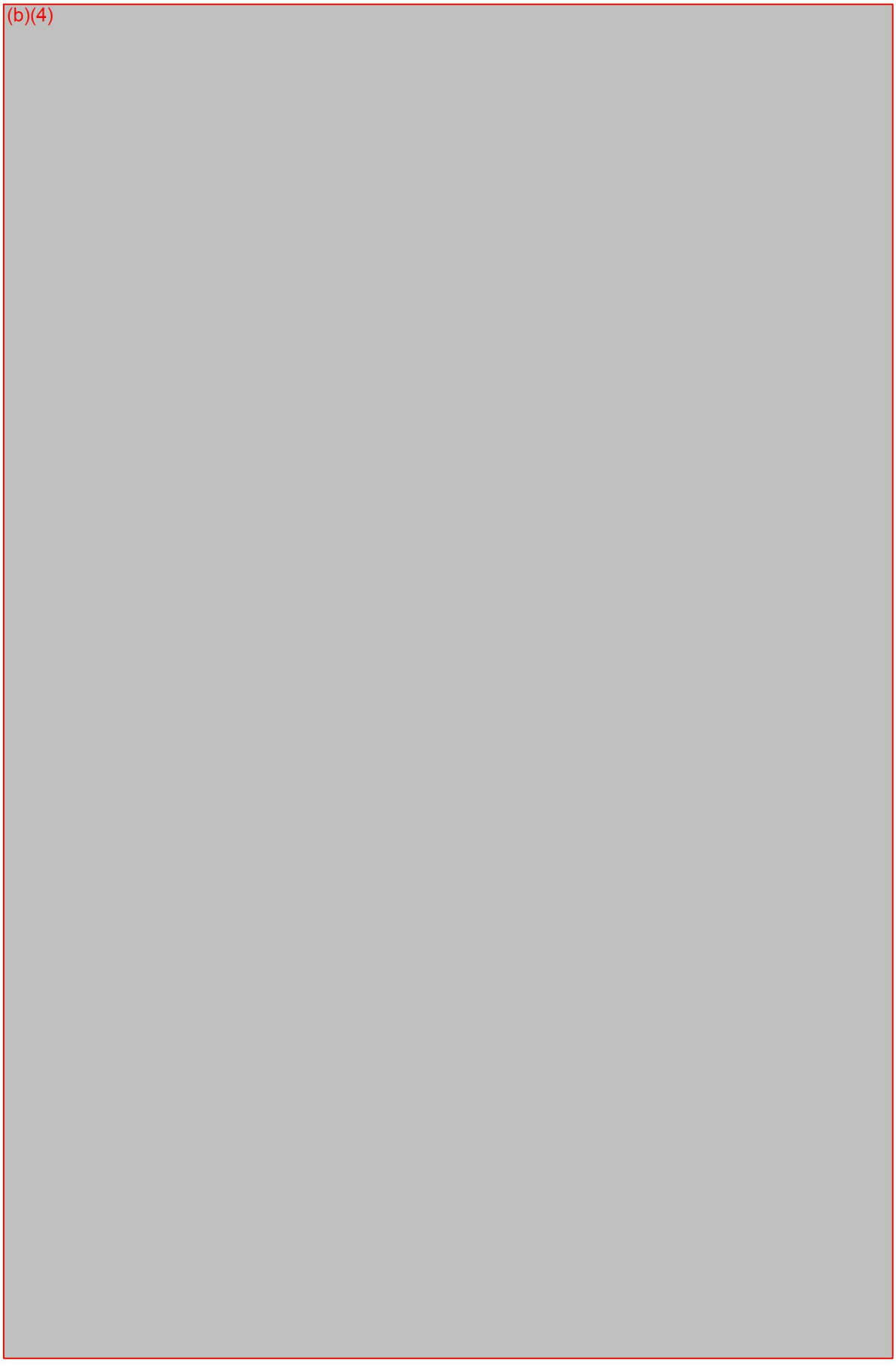
The engineering drawings for the spherical and aspherical single vision lenses, multifocal lens, toric lens and multifocal – toric lens are provided in Attachment A. The Company noted that "As noted in K073485, the substantial equivalence of the

(b)(4)

Manufacturing/control (pp. 80-81)

(b)(4)

9b


(b)(4)

(b)(4)

Manufacturing Flow Diagram:

A manufacturing flow diagram is provided in **Attachment B**. (p.B-2)

(b)(4)

Lens Inspection:

(b)(4)

Substantial Equivalence

Predicate Device(s)

Material:
VISTAKON® (narafilcon A) Contact Lens – K073485
(FDA Group I; low water, nonionic polymer (*Daily wear, single use*))

Indication, Wear Schedule:
VISTAKON® (etafilcon A) Contact Lenses– K962804
(*(Group IV; high water, ionic polymer)* Daily wear, single use)

The following comparison tables are provided for material comparison, parameter comparison, and indication for use comparison (pp.86, 87).

Material Comparison		
	Predicate Device	**Subject Device**
Product Name	VISTAKON® (narafilcon A) Contact Lens	VISTAKON® (narafilcon B) Contact Lens
Material USAN Name	narafilcon A	narafilcon 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® (narafilcon A) Contact Lens – K073485		**Subject Device** VISTAKON® (narafilcon 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

*Dk units: 10^{-11} $(cm^2/sec)(ml\ O_2/ml \times mmHg)$

Indications for Use Comparison			
	Predicate Devices		Subject Device
	VISTAKON® (narafilcon A) Contact Lens K073485	1-DAY ACUVUE® Brand (etafilcon A) Contact Lens K962804	VISTAKON® (narafilcon B) Contact Lens Unknown
Spherical - Intended Use	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.	Indicated for daily wear single use for the correction of refractive ametropia (myopia hyperopia, and presbyopia) in aphakic or non-aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.	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 - Intended Use	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.	Indicated for daily wear single use for the correction of distance and near vision in presbyopic, aphakic or non-aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less.	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 - Intended Use	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.	Indicated for daily wear single use for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D or less of astigmatism	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-Intended Use	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.	Indicated for daily wear single use for the correction of distance and near vision in presbyopic aphakic or non-aphakic persons with non-diseased eyes who may have 10.00D of astigmatism or less.	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.

(b)(4)

Property	Specification
Water Content, %	(b)(4)
Refractive Index @ 20°C	
*Dk, edge corrected	
Color	
Light Transmittance @ 380 - 780 nm, %	
Light Transmittance @ 316 - 380 nm, %	
Light Transmittance @ 280 - 315 nm, %	
Tensile Strength, psi	
Elongation, %	
Modulus, psi	
Toughness, in lb/in^3	
Dynamic Contact Angle (°), (DCA)	

*Dk units: 10^{-11}(cm^2/sec)(ml O_2/ml x mmHg)

Property	Predicate Device, measured (SD)	Predicate Device, labeled	Subject Device, measured (SD)	Subject Device, labeled
Water Content, %	47 n=9 (0.4)	46	48 n=9 (0.1)	48
Refractive Index @ 20°C	1.40 n=6 (0.00)	1.41	1.41 n=6 (0.00)	1.41
Dk*, edge corrected	96 n=4 (NA)	100	52 n=4 (NA)	55
Color	Blue n=1	Blue	Blue n=1	Blue
Light Transmittance @ 380-780nm, %	97.29 n=5 (0.30)	94 +/- 5%	96.1 n=5 (0.9)	94 +/- 5%
Light Transmittance @ 316-380nm, %	3.48 n=5 (0.21)	<10 %	3.7 n=5 (0.5)	<10 %
Light Transmittance @ 280-315nm, %	0.01 n=5 (0.00)	<1 %	0.1 n=5 (0.0)	<1 %
Tensile Strength, psi	94 n=12 (16)	NA	87 n=12 (31)	NA
Elongation, %	217 n=12 (53)	NA	190 n=12 (75)	NA
Modulus, psi	104 n=12 (10)	NA	109 n=12 (10)	NA
Toughness, (in lb/in^3)	116 n=12 (44)	NA	99 n=12 (69)	NA
Dynamic Contact Angle, °	57 n=5 (4)	NA	54 n=5 (10)	NA
Base Curve, mm	8.53 n=10 (0.04)	8.5	8.49 n=8 (0.03)	8.5
Diameter, mm	14.26 n=10 (0.03)	14.2	14.19 n=8 (0.02)	14.2
Power, diopters	-0.92 n=10 (0.04)	-1.00	-0.98 n=8 (0.03)	-1.00
Center Thickness, mm	0.085 n=10 (0.007)	NA	0.086 n=8 (0.004)	NA

*Dk units: 10^{-11}(cm^2/sec)(ml O_2/ml x mmHg)

Modifications of a contact lens material may have a significant impact on the performance characteristics of the approved/cleared lens. Therefore, a company should

(b)(4)

Packaging

(b)(4)

Shelf life

(b)(4)

Leachability

(b)(4)

Material	Lens Wt. µg/g		Method Overview
	narafilcon B	narafilcon A	
(b)(4)			

(b)(4)

Recommendation

The information provided in this 510(k) is inadequate to support a substantially equivalent determination for the VISTAKON® (narafilcon B) Contact Lens from a chemistry perspective. The following issues should be conveyed to the Company for resolution.

Formulation

1. (b)(4)

Specifications for contact lens properties

2. You summarized the lens property specification ranges for the VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV Blocker in the table below:

Property	Specification
Water Content, %	(b)(4)
Refractive Index @ 20°C	
*Dk, edge corrected	
Color	
Light Transmittance @ 380 - 780 nm, %	
Light Transmittance @ 316 - 380 nm, %	
Light Transmittance @ 280 - 315 nm, %	
Tensile Strength, psi	
Elongation, %	
Modulus, psi	
Toughness, in lb/in^3	
Dynamic Contact Angle (°), (DCA)	

*Dk units: 10^{-11}(cm^2/sec)(ml O_2/ml x mmHg)

(b)(4)

Packaging

3. (b)(4)

4.

(b)(4)

Manufacturing

5. (b)(4)

Substantial equivalence

6. (b)(4)

Property	Specification
Water Content, %	(b)(4)
Refractive Index @ 20°C	
*Dk, edge corrected	
Color	
Light Transmittance @ 380 - 780 nm, %	
Light Transmittance @ 316 - 380 nm, %	
Light Transmittance @ 280 - 315 nm, %	
Tensile Strength, psi	
Elongation, %	
Modulus, psi	
Toughness, in lb/in^3	
Dynamic Contact Angle (°), (DCA)	

*Dk units: 10^{-11}(cm^2/sec)(ml O_2/ml x mmHg)

Property	Predicate Device, measured (SD)	Predicate Device, labeled	Subject Device, measured (SD)	Subject Device, labeled
Water Content, %	47 n=9 (0.4)	46	48 n=9 (0.1)	48
Refractive Index @ 20°C	1.40 n=6 (0.00)	1.41	1.41 n=6 (0.00)	1.41
Dk*, edge corrected	96 n=4 (NA)	100	52 n=4 (NA)	55
Color	Blue n=1	Blue	Blue n=1	Blue
Light Transmittance @ 380-780nm, %	97.29 n=5 (0.30)	94 +/- 5%	96.1 n=5 (0.9)	94 +/- 5%
Light Transmittance @ 316-380nm, %	3.48 n=5 (0.21)	<10 %	3.7 n=5 (0.5)	<10 %
Light Transmittance @ 280-315nm, %	0.01 n=5 (0.00)	<1 %	0.1 n=5 (0.0)	<1 %
Tensile Strength, psi	94 n=12 (16)	NA	87 n=12 (31)	NA
Elongation, %	217 n=12 (53)	NA	190 n=12 (75)	NA
Modulus, psi	104 n=12 (10)	NA	109 n=12 (10)	NA
Toughness, (in lb/in^3)	116 n=12 (44)	NA	99 n=12 (69)	NA
Dynamic Contact Angle, °	57 n=5 (4)	NA	54 n=5 (10)	NA
Base Curve, mm	8.53 n=10 (0.04)	8.5	8.49 n=8 (0.03)	8.5
Diameter, mm	14.26 n=10 (0.03)	14.2	14.19 n=8 (0.02)	14.2
Power, diopters	-0.92 n=10 (0.04)	-1.00	-0.98 n=8 (0.03)	-1.00
Center Thickness, mm	0.085 n=10 (0.007)	NA	0.086 n=8 (0.004)	NA

*Dk units: 10^{-11}(cm^2/sec)(ml O_2/ml x mmHg)

In your substantial equivalence discussion (p. 85- 87, Section 12), you did not (b)(4)

(b)(4)

Shelf life

7. (b)(4)

Labeling

8. (b)(4)

*** Deficiency marker

File name: k100349 Chemistry Review.doc

111

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: April 15, 2010

From: Susanna Jones, Toxicologist, ODE/DONED/ICNB, WO66-2468

Subject: Biocompatibility Review of K100349
Johnson & Johnson Vision Care, Inc.
VISTAKON® (narafilcon B) Contact Lens Visibility Tinted, with UV Blocker

To: Record, K100349

Indications for Use:

The VISTAKON® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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.

Submitted: The sponsor is seeking clearance to market the VISTAKON® (narafilcon B) Contact Lenses. The lenses are made from a modified lens material, narafilcon B. The lens material is a silicone hydrogel material containing an internal wetting agent, and 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.

Substantial Equivalence: The sponsor is claiming as the predicate device the narafilcon A contact lens (K073485). The following table compares the chemical composition of the narafilcon A and narafilcon B materials:

Material	Function	Purity (%)	K100349		K073485	
			Wt (%)	Mole (%)	Wt (%)	Mole (%)
(b)(4)						

Comment: The chemical composition of narafilcon B is essentially the same as the predicate, narafilcon A, except for the proportions of the three monomers.

Biocompatibility Testing: Biocompatibility testing was conducted for the VISTAKON® (narafilcon A) Contact Lens (reference K073485 cleared on March 3, 2008). The sponsor asserts

(b)(4)

In addition, the sponsor conducted the following verification tests to demonstrate that the lens (narafilcon B) is non-irritant and non-toxic:

(b)(4)

Additionally, the sponsor previously conducted the following testing on the plastic packaging materials:

- (b)(4)
-
-

Comments:

- The test results provide reasonable assurance that the device and its packaging materials are biocompatible.
- (b)(4)

Conclusion/Recommendation: From a biocompatibility perspective, this submission can be found substantially equivalent.

K100349
510(k) Clinical Review

Date:	March 24, 2010
From:	Marc Robboy Marc Robboy
To:	The Record
Through:	Karen Warburton, Team Leader
Subject:	K100349 Premarket Notification
Device:	VISTAKON® (narafilcon B) Contact Lens Visibility Tinted, with UV Blocker
Contact:	Catherine C. Dillon Project Leader I Regulatory Affairs Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Suite 100 Jacksonville, FL 32256 904-443-3180 cdillon9@its.jnj.com

Background:
The purpose of this submission is to provide notification of intent to market a new daily wear soft contact lens, VISTAKON® (narafilcon B) Contact Lens Clear and Visibility Tinted, with UV blocker. The VISTAKON® (narafilcon 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® (narafilcon 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 lens is supplied in a sterile state, packaged in a buffered saline solution with methyl ether cellulose. The composition of the lens is 52% narafilcon B and 48% water by weight when hydrated and stored in the buffered saline solution. The predicate devices referenced include VISTAKON® (narafilcon A) Contact Lens – K073485, and VISTAKON® (etafilcon A) Contact Lenses – K962804.

Indications for Use:
The VISTAKON® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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.

Clinical Testing:
In order to support substantial equivalence, a one-month clinical study was undertaken to evaluate the safety and efficacy of the VISTAKON® (narafilcon B) Contact Lens for single use daily wear only.

The clinical report is presented in attachment H. The IRB-approved protocol is included as an appendix to the report. The (b)(4) study investigators are listed on page H-7. The study was conducted under the approval of the (b)(4)

Study Design:
The (b)(4) investigator, 1-month daily disposable clinical study was a (b)(4)
(b)(4)

The objective of this study was to evaluate the single use daily wear clinical performance of the VISTAKON® Investigational (narafilcon) contact lens compared to the *1-DAY ACUVUE® Brand Contact Lenses*. The sponsor intended to show the VISTAKON® Investigational (narafilcon) contact lens is clinically substantially equivalent to the control lens, with respect to Slit Lamp Findings, Symptoms, Visual Acuity, and Average Wear Time. (b)(4) (b)(4)

The performance parameters that were monitored and evaluated included adverse events, keratometry changes, reasons for discontinuation, and number and reasons for unscheduled lens replacements.

Study Endpoints

(b)(4)

In this clinical trial, the VISTAKON® narafilcon B (Test) lenses were compared to the 1-Day ACUVUE® Brand Contact Lenses (Control). All lenses worn during the study were worn daily disposable (less than 24 hours while awake and then disposed). Although there were no solutions dispensed, each subject was provided with preservative free rewetting drops to use as needed. There was a ratio of 1 to 1 between the Test lens and the Control lens subjects, respectively. Scheduled study visits were at Initial/ Trial Fitting, 1 week, and 1 month.

Comment:
The sample size and Test: Control ratio satisfy the recommendations in the FDA Guidance.

Enrollment Criteria:
Inclusion and Exclusion criteria are described on pages H-21 and H-22.

Comment:
The criteria are similar to those typically used in studies like this.

Data Analysis:

(b)(4)

Comment:

These deviations are considered minor.

Subject Disposition:

(b)(4)

(b)(4)

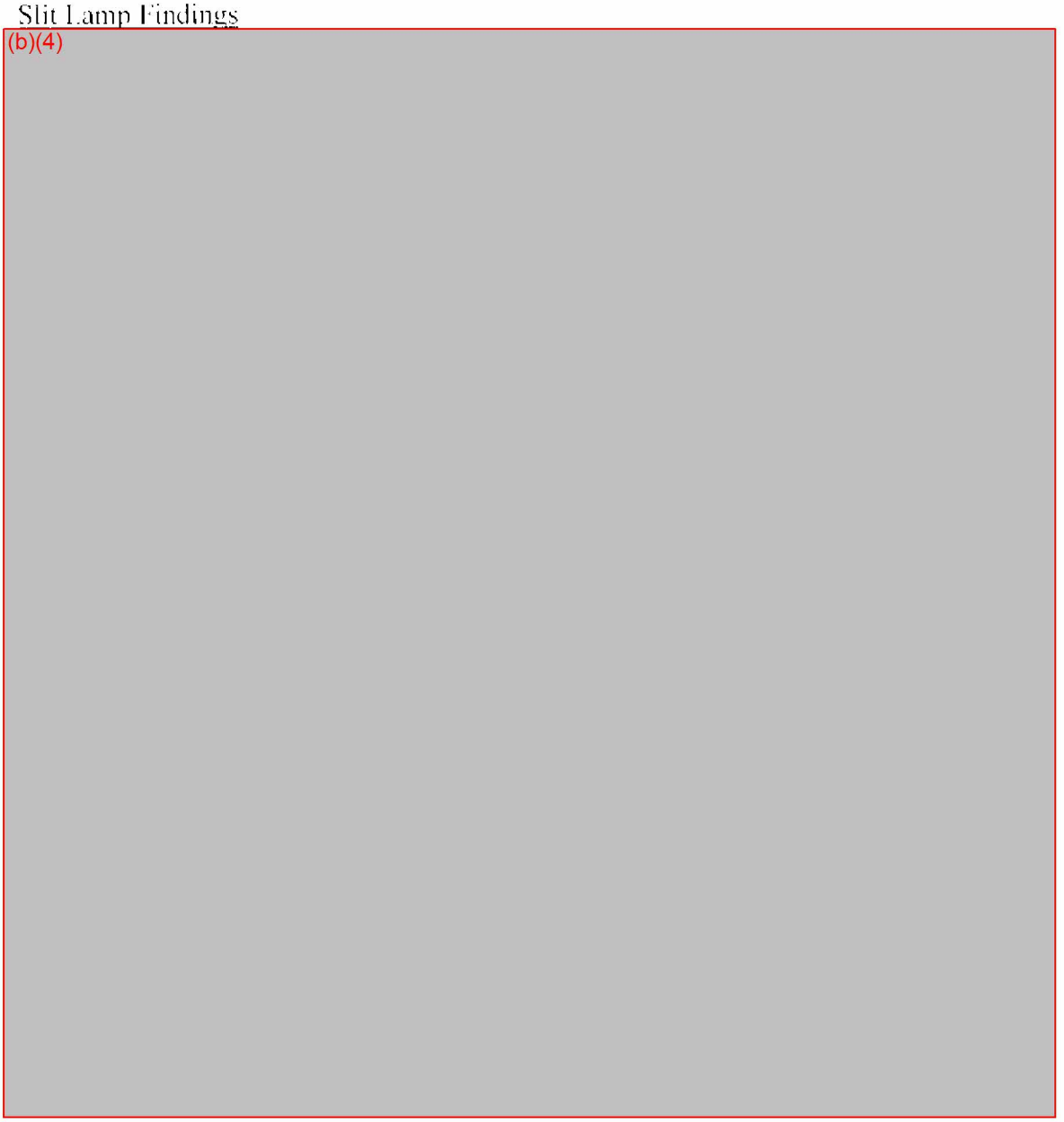
Comment:
This distribution of previous vs new wearers is a good mix.

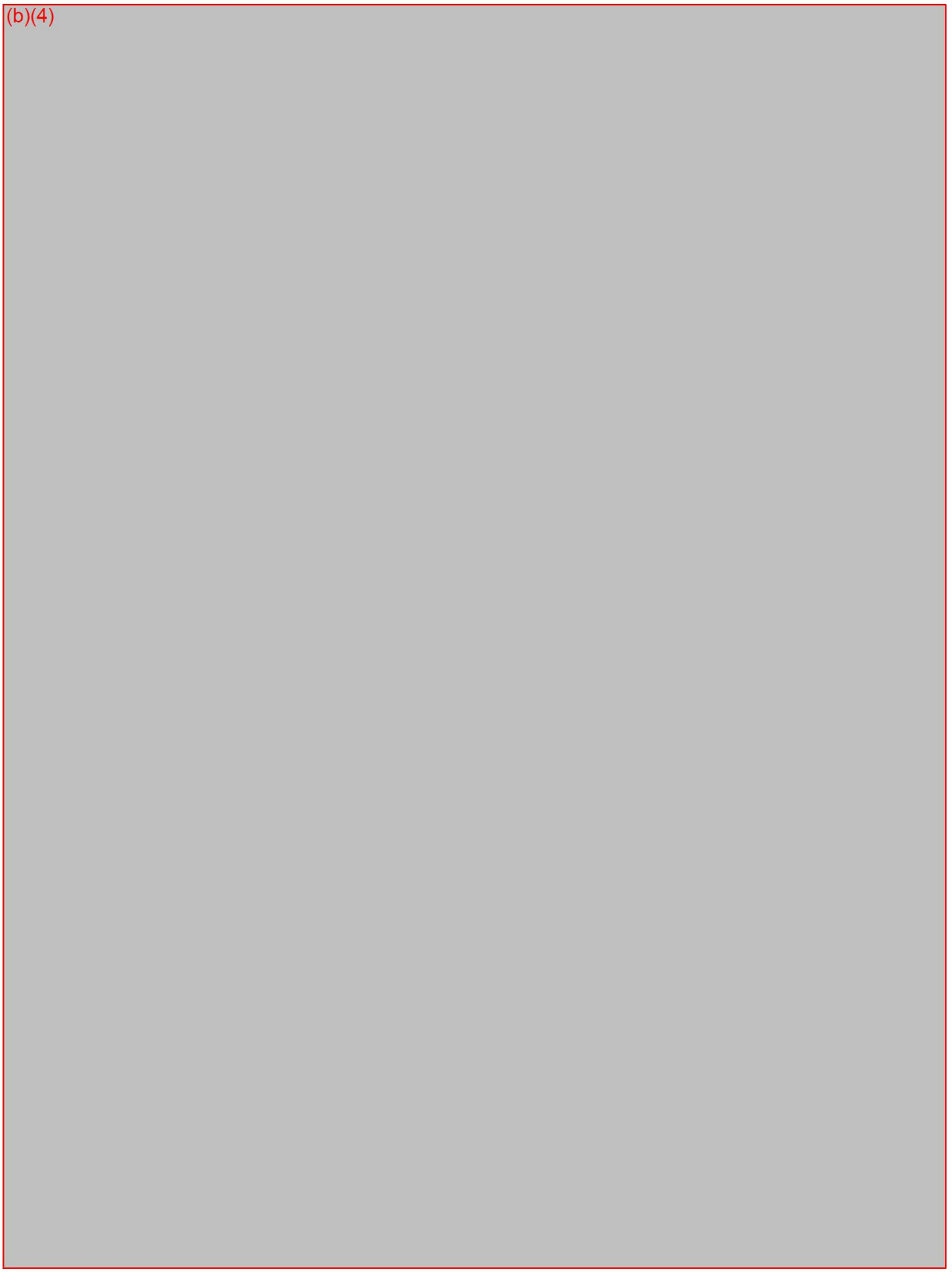
STUDY RESULTS (Pages H-34 to H-48)

Safety
Adverse Events:
No adverse events (serious or significant) were reported for the Test or the Control groups.

Slit Lamp Findings

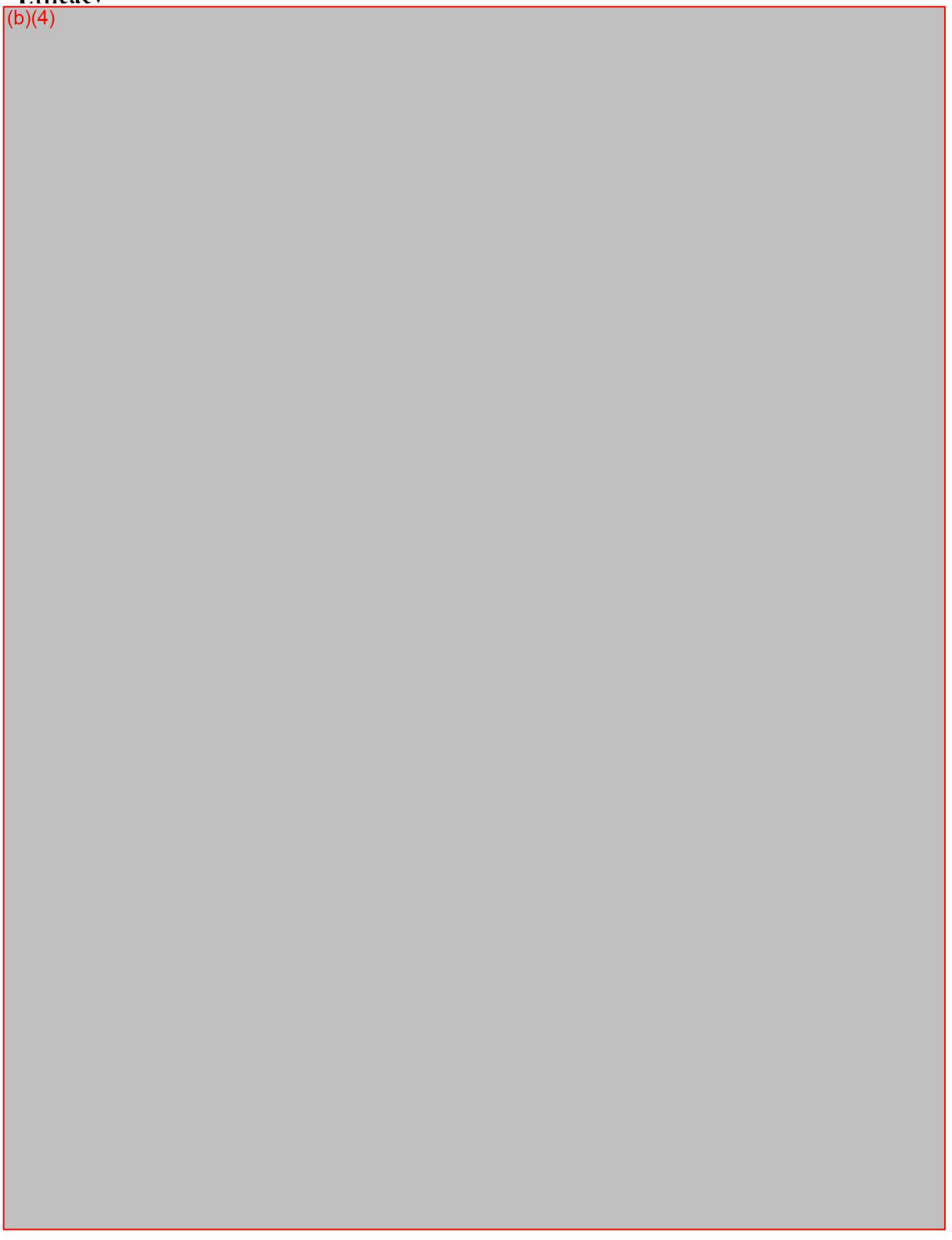
(b)(4)

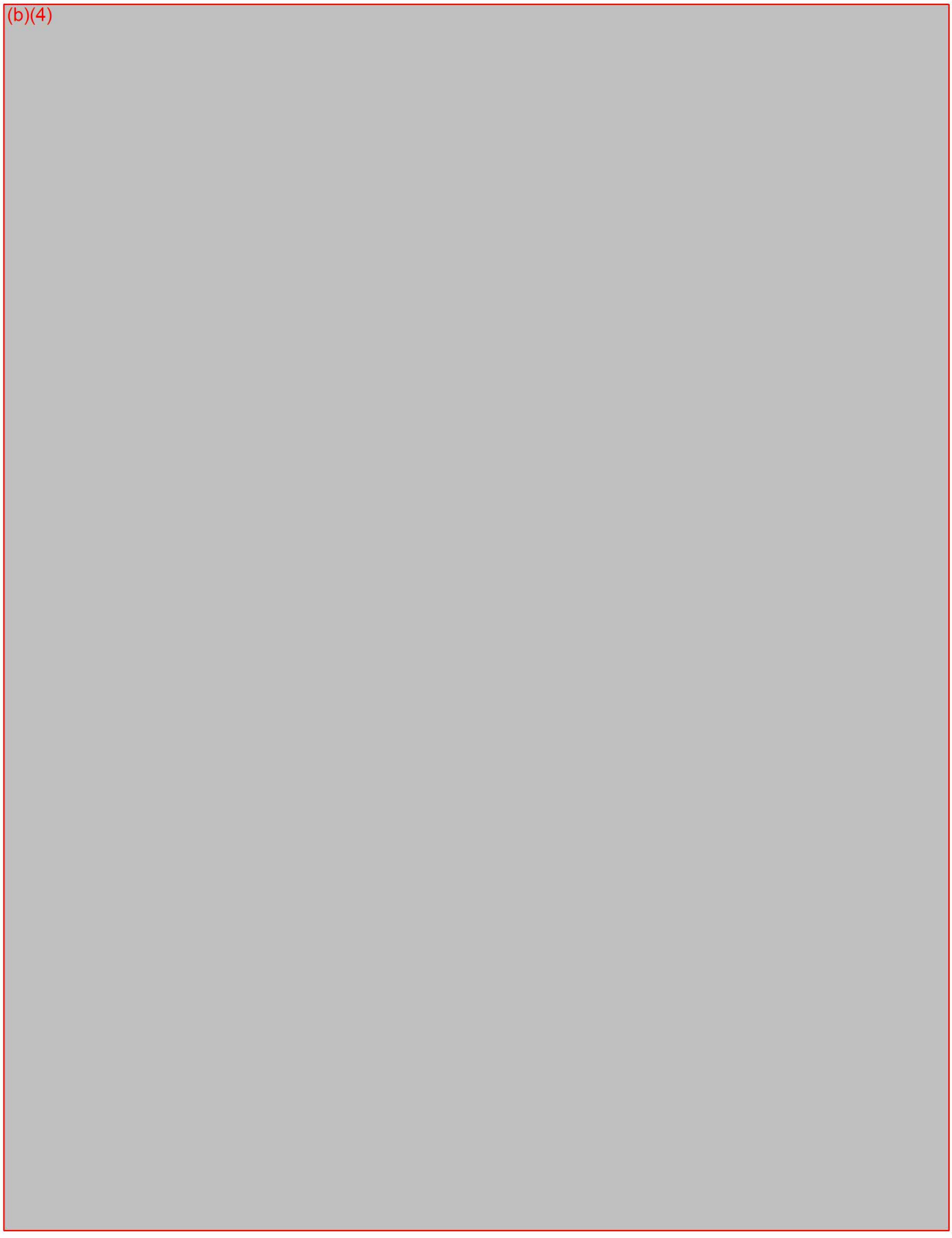



(b)(4)

Efficacy

(b)(4)




(b)(4)

Conclusion/ Recommendations:
As presented, this application does not provide sufficient information regarding the device under review to render a decision of substantial equivalence. The sponsor should address the following deficiency:

(b)(4)

Warburton, Karen

From: Dillon, Catherine [VISUS] [CDillon9@its.jnj.com]
Sent: Wednesday, February 24, 2010 10:27 AM
To: Robboy, Marc
Cc: Warburton, Karen; visusinternalrooms.globalregulatoryaffairs.CateSALSAe-mails@eroom.na.jnj.com
Subject: RE: K100349 narafilcon B Contact Lens
Attachments: Red-Lined VISTAKON (narafilcon B) Generic PI and FIG.pdf; Red-Lined VISTAKON (narafilcon B) PATIENT INSTRUCTION GUIDE.pdf

Dear Dr. Robboy,

As requested, please find the red-lined labeling attached.

Should you require any additional information, please let me know.

Thank you,

Cate

Catherine Dillon
Project Leader I, Regulatory Affairs
Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway, Suite 100
Jacksonville, Florida 32256
Phone: (904) 443-3180
Fax: (904) 443-1424
Email: cdillon9@its.jnj.com

From: Robboy, Marc [mailto:Marc.Robboy@fda.hhs.gov]
Sent: Tuesday, February 23, 2010 2:33 PM
To: Dillon, Catherine [VISUS]
Cc: Warburton, Karen
Subject: K100349 narafilcon B Contact Lens

Catherine:
You state on page 91 of 112 that your predicate for the labeling is the narafilcon A lens labeling that we cleared under K073485. In order to facilitate my labeling review, can you please provide me with a red-line version of the K100349 labeling (an electronic copy will suffice), which would clearly indicate any differences from the narafilcon A labeling?

Thanks,
Marc Robboy

Marc Robboy, OD
Marc Robboy/ Optometrist/ Clinical Reviewer

US Food & Drug Administration/ Center for Devices and Radiological Health
Division of Ophthalmic, Neurological and ENT Devices
Intraocular, Cornea and Neuromaterials Branch

White Oak Building 66, Room 2256
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 301.796.6860
Fax: 301.847.8126
Email: marc.robboy@fda.hhs.gov

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PACKAGE INSERT
&
FITTING AND PATIENT MANAGEMENT GUIDE

IMPORTANT: Please read carefully and keep this information for future use.

This Package Insert is intended for the Eye Care Professional, but should be made available to patients upon request. The Eye Care Professional should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

VISTAKON® (narafilcon B) Contact Lenses (Spherical)
VISTAKON® (narafilcon B) Contact Lenses (Multifocal)
VISTAKON® (narafilcon B) Contact Lenses (Toric)
VISTAKON® (narafilcon B) Contact Lenses (Multifocal-Toric)

Visibility Tinted with UV Blocker
For Single Use Daily Wear Only

VISTAKON® (narafilcon B) Contact Lenses (Spherical); VISTAKON® (narafilcon B) Multifocal Contact Lenses; VISTAKON® (narafilcon B) Toric Contact Lenses VISTAKON® (narafilcon B) Multifocal-Toric Contact Lenses; Soft (hydrophilic) Contact Lenses- Visibility Tinted with UV Blocker for Daily Wear Single Use only.

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	See Instruction Leaflet
	Use By Date (expiration date)
LOT	Batch Code
STERILE	Sterile Using Steam or Dry Heat
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
	UV Blocking
0086	
	Fee Paid for Waste Management
	Peel Back Foil
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner
C.T.	Center Thickness
	Visibility Tinted Lens Orientation Correct
	Visibility Tinted Lens Inside Out
CYL	Cylinder Power
AXIS	Axis
LOW	"Low" near ADD
MID	"Medium" near ADD
HIGH	"High" near ADD

Spherical Lenses For:
Myopia, Hyperopia, Phakic or Aphakic

Multifocal Lenses For:
Presbyopia, Phakic or Aphakic

Toric Lenses For:
Myopic Astigmatism, Hyperopic Astigmatism, Mixed Astigmatism, Phakic or Aphakic

Multifocal-Toric Lenses For:
Presbyopic Astigmatism , Phakic or Aphakic

CAUTION: Federal U.S.A law restricts this device to sale by or on the order of a licensed practitioner.

DESCRIPTION

The VISTAKON® (narafilcon – B) Soft (hydrophilic) Contact Lenses are available as a Spherical, Multifocal, Toric or a Multifocal-Toric lens. The lenses are made of a silicone hydrogel material containing an internal wetting agent with visibility tinted UV absorbing monomer. The VISTAKON® (narafilcon – B) Contact Lens Visibility Tinted with UV Blocker is tinted blue using Reactive Blue Dye #4 to make the lenses 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 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

Lens Properties:

- **Specific Gravity: 1.07**
- **Refractive Index: 1.41**
- **Light Transmittance: 85% minimum**
- **Surface Character: Hydrophilic**
- **Water Content: 48%**
- **Oxygen Permeability:**

VALUE	METHOD
55 x 10^{-11} (cm^2/sec) (ml O2/ml x mm Hg) at 35°C	Polarographic edge and boundary corrected

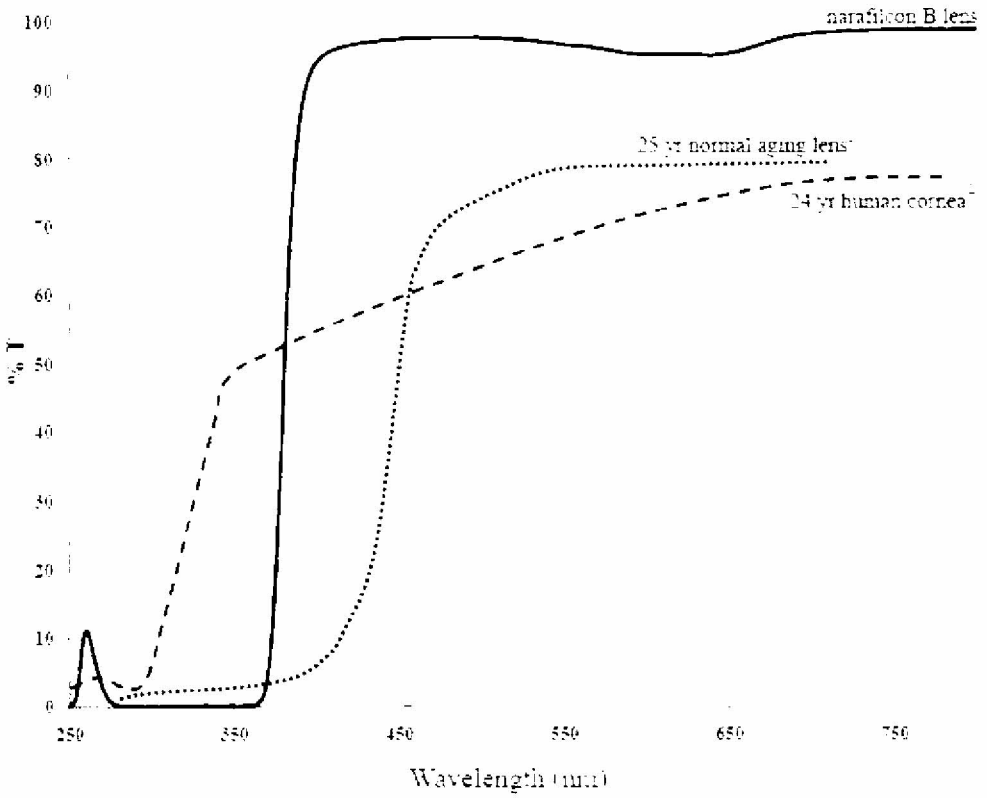
Lens Parameters:

The VISTAKON® (narafilcon – B) Contact Lenses are a hemispherical and/or hemitoric shell available within the following dimensions:

Diameter Range:	12.0mm to 15.0mm	
Center Thickness:	Low minus lens – (0.085mm)	
	Plus lens – varies with power (e.g., +3.00D: 0.170mm)	
Base Curve Range:	7.80mm to 10.00mm	
Power Range:		
	Spherical Power: Daily Wear	-20.00D to +20.00D
	Multifocal ADD Powers:	+0.25D to +4.00D
	Multifocal-Toric ADD Powers:	+0.25D to +4.00D
	Cylinder Power:	-0.25D to -10.00D
	Axis:	2.5° to 180

Transmittance Curves

VISTAKON® (narafilcon - B) Contact Lens Visibility Tinted with UV Blocker, 24 yr. old human cornea and 25 yr. old human crystalline lens



* The data was obtained from measurements taken through the central 3-5mm portion for the thinnest marketed lens (-1.00D lens, 0.085mm center thickness).

1. Lerman, S., Radiant Energy and the eye, MacMillan, New York, 1980, p.58, figure 2-21

2. Waxler, M. Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.10, figure 5

WARNING: UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.

ACTIONS

In its hydrated state, the VISTAKON® (narafilcon - B) Contact Lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

The transmittance characteristics are less than 1% in the UVB range of 280nm to 315nm and less than 10% in the UVA range of 316nm to 380nm for the entire power range.

Note: Long term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV blocking contact lenses help provide

protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your Eye Care Professional for more information.

INDICATIONS (USES)

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

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

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

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

Eye Care Professionals should prescribe the lenses for daily wear single use only (see "Wearing Schedule"). The lenses are to be discarded upon removal. Therefore, no cleaning or disinfection is required.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the VISTAKON (narafilcon B) Contact Lens when any of the following conditions exist:

- Inflammation or infection in or around the eye or eyelids
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
- Any previously diagnosed condition that makes contact lens wear uncomfortable.
- Severe dry eye
- Reduced corneal sensitivity (corneal hypoesthesia)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or surrounding tissues (adnexa) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated

WARNINGS

Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products, including lens cases, are essential for the safe use of these products
- Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- Studies have shown that the risk of ulcerative keratitis is greater for extended wear contact lens users than for daily wear users[1].
- When daily wear users wear their lenses overnight (outside the approved indication), the risk of ulcerative keratitis is greater than among those who do not wear them overnight.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.
- Studies have shown that the risk of ulcerative keratitis among contact lens users who smoke is greater than among non-smokers.

If patients experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, they should be instructed to immediately remove their lenses and promptly contact their Eye Care Professional. It is recommended that contact lens wearers see their Eye Care Professional routinely as directed.

[1] New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

PRECAUTIONS

Special Precautions for Eye Care Professionals:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the Eye Care Professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness and optic zone diameter.

  The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing Eye Care Professional.

- Patients who wear the VISTAKON® (narafilcon B) Contact Lenses to correct presbyopia using Monovision or patients who use the VISTAKON® Multifocal Contact Lenses or the VISTAKON® Multifocal-Toric Contact Lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Eye Care Professionals should instruct the patient to remove the lenses immediately if the eyes become red or irritated.

Eye Care Professionals should carefully instruct lens wear patients about the following care regimen and safety precautions:

Handling Precautions:

- Before leaving the Eye Care Professional's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.
- **DO NOT** use if the sterile blister package is opened or damaged.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and or injury to the eye.
- Carefully follow the handling, insertion, removal, and wearing instructions in the "Patient Instruction Guide" for the VISTAKON® Contact Lens and those prescribed by the Eye Care Professional.
- Always handle lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens and the packing solution into the hand.
- Do not touch the lens with fingernails.

Lens Wearing Precautions:

- If the lens sticks (stops moving) on the eye, follow the recommended directions in "Care for a Sticking Lens". The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her Eye Care Professional.
- Never wear lenses beyond the period recommended by the Eye Care Professional.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the Eye Care Professional about wearing lenses during sporting activities, especially swimming and other water sports. Exposing contact lenses to water during swimming or while in a hot tub may increase the risk of eye infection from microorganisms.
- Always discard lenses worn as prescribed by the Eye Care Professional.

Lens Care Precautions:
The patient should be informed that no cleaning or disinfection is needed with daily wear single use only lenses. Patients should always dispose of lenses when removed and have replacement lenses or spectacles available.

Other Topics to Discuss with Patients:
- Always contact the Eye Care Professional before using any medicine in the eyes.
- Certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers and those for motion sickness, may cause dryness of the eye, increased lens awareness or blurred vision. Should such conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

Who Should Know That the Patient is Wearing Contact Lenses?
- Inform the doctor (Health Care Professional) about being a contact lens wearer.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

ADVERSE REACTIONS
The patient should be informed that the following problems may occur when wearing contact lenses:

- The eye may burn, sting and or itch.
- There may be less comfort than when the lens was first placed on the eye.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers and corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.
- There may be excessive watering, unusual eye secretions, or redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, photo-phobia, or dry eyes may also occur if the lenses are worn continuously or for too long a time.

The patient should be instructed to conduct a simple 3-part self-examination at least once a day. They should ask themselves:

- How do the lenses feel on my eyes?
- How do my eyes look?
- Have I noticed a change in my vision?

If the patient reports any problems, he or she should be instructed to IMMEDIATELY REMOVE THE LENS.

If the discomfort or problem stops, the patient should then look closely at the lens.

If the lens is in any way damaged, the patient SHOULD NOT put the lens back on the eye. The patient should discard the lens and apply a new fresh lens on the eye.

If the lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, he or she should be instructed to dispose of the lens and apply a new fresh lens.

If the problem continues, the patient SHOULD NOT put the lens back on the eye but IMMEDIATELY CONSULT HIS OR HER EYE CARE PROFESSIONAL.

The patient should be instructed NOT to use a new lens as self-treatment for the problem.

The patient should be advised that when any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. He or she should be instructed to seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING GUIDELINES

I. GENERAL FITTING INSTRUCTIONS

VISTAKON® (narafilcon A-B) Contact Lens (Spherical)
VISTAKON® (narafilcon A-B) Contact Lens (Toric)
VISTAKON® (narafilcon A-B) Contact Lens (Multifocal)
VISTAKON® (narafilcon A-B) Contact Lens (Multifocal-Toric)

A. Patient Selection:

Patients selected to wear VISTAKON® (narafilcon A-B) Contact Lenses should be chosen based on:

- Motivation to wear lenses
- Ability to follow instructions regarding lens wear care
- General health
- Ability to adequately handle and care for the lenses
- Ability to understand the risk and benefits of lens wear.

Patients who do not meet the above criteria should not be provided with contact lenses.

B. Pre-fitting Examination

Initial evaluation of the patient should begin with a thorough case history to determine if there are any contraindications to contact lens wear. During the case history, the patient's visual needs and expectations should be determined as well as an assessment of their overall ocular, physical, and mental health.

Preceding the initial selection of trial contact lenses, a comprehensive ocular evaluation should be performed that includes, but is not limited to, the measurement of distance and near visual acuity, distance and near refractive prescription (including determining the preferred reading distance for presbyopes), keratometry and biomicroscopic evaluation.

Based on this evaluation, if it is determined that the patient is eligible to wear VISTAKON® (narafilcon A-B) Contact Lenses, the Eye Care Professional should proceed to the appropriate lens fitting instruction outlined below.

C. Initial Power Determination

A spectacle refraction should be performed to establish the patient's baseline refractive status and to guide in the selection of the appropriate lens power. Remember to compensate for vertex distance if the refraction is greater than ±4.00 D.

D. Base Curve Selection (Trial Lens Fitting)

For the VISTAKON® (narafilcon A-B) Spherical and Toric lenses, the 8.5mm/14.2mm Contact Lens should be selected for myopic patients regardless of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status. For the VISTAKON® (narafilcon A-B) Multifocal and Multifocal-Toric Contact Lenses, the initial lens should be selected from the currently available base curves.

A VISTAKON® (narafilcon A-B) trial lens should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses.

1. Criteria of a Properly Fit Lens

   A properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement to provide tear exchange under the contact lens with the blink and be comfortable. The lens should move freely when manipulated digitally with the lower lid, and then return to its properly centered position when released. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

2. Criteria of a Flat Fitting Lens

   A flat fitting lens may exhibit one or more of the following characteristics: decentration, incomplete corneal coverage (i.e., limbal exposure), excessive movement with the blink and/or edge standoff. If the VISTAKON® (narafilcon A-B) Contact Lens is judged to be flat fitting, it should not be dispensed to the patient.

3. Criteria of a Steep Fitting Lens

   A steep fitting lens may exhibit one or more of the following characteristics: insufficient movement with the blink, conjunctival indentation and resistance when pushing the lens up digitally with the lower lid. If the VISTAKON® (narafilcon A-B) Contact Lens is judged to be steep fitting, it should not be dispensed to the patient.

If the initial VISTAKON® (narafilcon A-B) base curve is judged to be flat or steep fitting, the alternate base curve, if available, should be trial fit and evaluated after the patient has adjusted to the lens. The lens should move freely when manipulated digitally with lower lid, and then return to a properly centered position when released. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

II. SPHERICAL LENS FITTING GUIDELINES

A spherical over-refraction should be performed to determine the final lens power after the lens fit is judged acceptable. The spherical over-refraction should be combined with the trial lens power to determine the final lens prescription. The patient should experience good visual acuity with the correct lens power unless there is excessive residual astigmatism.

Example 1:		
Diagnostic lens:		-2.00 D
	Spherical over-refraction	-0.25 D
	Final lens power:	-2.25 D

Example 2:		
Diagnostic lens:		-2.00 D
	Spherical over-refraction	+0.25 D

	Final lens power:	-1.75 D

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow up information in **PATIENT MANAGEMENT**).

III. TORIC FITTING GUIDELINES

Although most aspects of the fitting procedure are identical for all types of soft contact lenses, including torics, there are some additional steps and/or rules to follow to assure the proper fit of toric lenses.

The only new steps you must follow in prescribing the VISTAKON® (narafilcon A B) Toric Contact Lenses are that you must determine the stability, repeatability and drift angle of the lens axis so that you can prescribe the correct lens axis for your patient.

A. How to Determine Lens Cylinder and Axis Orientation for VISTAKON® Toric Lenses

1. Locate the Orientation Marks

To help determine the proper orientation of the toric lens, you'll find two primary marks about 1mm from the lens edge representing the vertical position on opposite ends of the lens at 6 and 12 o'clock (Fig. 1). Because of the lens' ballasting system, either mark can represent the vertical position – there is no "top" and "bottom" as in a prism-ballasted lens. You don't need to view both marks to assess orientation; simply look for the 6 o'clock mark as you would with a prism-ballasted lens.

Figure 1

You'll need a biomicroscope and a 1mm or 2mm parallelepiped to highlight the marks when the lens is fitted to the eye. There are a number of techniques you can use to improve the visibility of the 6 o'clock mark. With your parallelepiped and medium magnification (10x or 15x), slowly pan down the lens, looking just below the direct illumination at the retroilluminated area. Backlighting the mark this way should make them more visible. Sometimes manipulating the lower lid may be necessary to uncover the mark.

2. Observe Lens Rotation and Stability

Observe the position and stability of the "bottom" mark. It usually stabilizes at the 6 o'clock position. If it does, calculation of the lens power will be straightforward. The 6 o'clock position is not a "must", however; the absolute requirement is that the axis position be stable and repeatable.

The mark may stabilize somewhat left or right (drift) of the vertical meridian and still enable you to fit a toric lens for that eye, as long as the lens always returns to the same "drift axis" position after settling. The deviation can be compensated for in the final prescription. Your objective is to ensure that whatever position the initial lens assumes near 6 o'clock, this position must be stable and repeatable. With full eye movement or heavy blink, you may see the marks swing away, but they must return quickly to the original stable position. If the lens does not return quickly, you may need to select a different lens.

Assessing Rotation

Imagine the eye as a clock dial and every hour represents a 30° interval. If the orientation mark of the initial lens stabilizes somewhat left or right of the vertical position, the final lens

will orient on the eye with the same deviation. You can use an axis reticule in the slit lamp or use a line-scribed lens in a spectacle trial frame to measure or estimate the "drift angle" of the cylinder axis.

To compensate for this "drift", measure or estimate the "drift", then add or subtract it from the refractive axis to determine the correct cylinder axis. Use the LARS (Left Add, Right Subtract) method to determine which direction to compensate.

B. How to determine the Final Lens Power for VISTAKON® (narafilcon A B) Toric Contact Lens

When the diagnostic lens has its axis aligned in the same meridian as the patient's refractive axis, a spherocylindrical over-refraction may be performed and visual acuity determined. However, in the case of crossed axes, such as when the diagnostic lens axis is different from the patient's refractive axis, it is not advisable to over-refract because of the difficulty in computing the resultant power.

In fitting contact lenses, it is customary to prescribe the full power in the sphere. In the cylinder, however, any lens rotation is visually disturbing to the patient, so it's more practical to prescribe as weak a cylinder as possible. So, here is how to determine the final lens power.

For the Sphere:

If sphere alone or combined sphere and cylinder Rx ≥ +4.00D, compensate for vertex distance. If sphere alone or combined sphere and cylinder Rx ≤ +4.00D, vertex compensation is not necessary.

For the Cylinder:

Adjust the axis by the drift angle using LARS. Choose a cylinder that is ± 0.25D from the refractive cylinder.

Case Examples

Example 1

Manifest (spectacle) refraction:
O.D. 2.50 -1.25 x 180 20/20
O.S. 2.00 -1.00 x 180 20/20

Choose a diagnostic lens for each eye with an axis as close to 180° as possible. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate, based on the patient's initial response to the lens.

Check the orientation of the axis mark. If the bottom axis mark is in the 6 o'clock position on both eyes, choose the appropriate cylinder as listed previously.

Here is the Rx Prescribed Ordered:
O.D. -2.50 -1.25 x 180
O.S. 2.00 -0.75 x 180

Example 2

Manifest (spectacle) refraction:
O.D. 3.00 -1.00 x 90 20/20
O.S. 4.75 -2.00 x 90 20/20

Choose diagnostic lenses of -3.00 -0.75 x 90 for the right eye and –4.50 -1.75 x 90 for the left eye, the nearest lenses available to the spherical power and axis needed. Place the lens on each eye and allow a minimum of 5 minutes for it to equilibrate. The orientation mark on the right lens rotates left from the 6 o'clock position by 10°.

The fitting indicates the following:

Right Eye

Compensate the 10° axis drift by adding it to the manifest refraction axis. Here is the Rx prescribed:
O.D. –3.00 - 0.75 x 100

Left Eye

The lens on the left eye shows good centration, movement and a consistent tendency for the mark to drift right by 10° from the 6 o'clock position following a forced blink.

Since the manifest refraction called for a power of -4.75D, adjust for the vertex distance and reduce the sphere by 0.25D and prescribe the -1.75D cylinder. Compensate for the 10° axis drift by subtracting it from the manifest refraction. Here is the Rx prescribed:
O.S. –4.50 - 1.75 x 80

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow up information in **PATIENT MANAGEMENT**).

IV. MULTIFOCAL FITTING GUIDELINES

A. Presbyopic Needs Assessment & Patient Education

Multifocal contact lenses may produce compromise to vision under certain circumstances and the patient should understand that they might not find their vision acceptable in specific situations (i.e., reading a menu in a dim restaurant, driving at night in rainy/foggy conditions, etc.). Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments. Occupational and environmental visual demands should be considered. If the patient requires critical visual acuity and stereopsis, it should be determined by trial whether this patient can function adequately with the VISTAKON® (narafilcon B) Multifocal Contact Lens. VISTAKON® (narafilcon B) Multifocal Contact Lens wear may not be optimal for such activities as:

1. visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
2. driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with the VISTAKON® (narafilcon B) Multifocal Contact Lens should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

VISTAKON® (narafilcon B) Multifocal Contact Lenses are not recommended for patients who have -1.00 D or greater of refractive cylinder as this level of uncorrected cylinder may lead to additional visual compromise.

VISTAKON® (narafilcon B) Multifocal Contact Lenses come in the following ADD powers:
Lens "LOW" = "low" near ADD lens

Lens "MID" – "medium" near ADD lens
Lens "HIGH" – "high" near ADD lens

VISTAKON® (narafilcon A B) Multifocal Contact Lenses Fitting Instructions

Step 1	Determine: - Eye dominance (the methods described in MONOVISION SPHERE AND TORIC FITTING GUIDELINES may be used) - Spherical equivalent distance prescription (vertex corrected if necessary and rounded to less minus if between powers) - Near ADD
Step 2	Select the initial trial lens as follows: - For each eye select the trial lens distance power that is closest to the patient's distance spherical equivalent. Select the near power of the lens based on the patients ADD range as follows: ADD: +0.75 to +1.25 use a "LOW" near ADD lens on each eye ADD: +1.50 to +1.75 use a "MID" near ADD lens on each eye ADD: +2.00 to +2.50 use a "HIGH" near ADD lens on each eye
Step 3	Allow the lens to settle for a minimum 10 minutes.
Step 4	- Assess distance and near vision binocularly and monocularly. - Demonstrate the vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate and near. - Make adjustments in power as necessary (see **Multifocal Troubleshooting** below). The use of hand-held trial lenses is recommended. - If distance and near vision are acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow up information in PATIENT MANAGEMENT).

C. Multifocal Troubleshooting

Unacceptable Near Vision:

Determine the amount of additional plus, or less minus, over one or both eyes that is acceptable while checking the effect on distance and near vision. If vision is still not acceptable change the non-dominant eye to the next highest ADD power.

Unacceptable Distance Vision:

Determine the amount of additional minus, or less plus, over one or both eyes that is acceptable while checking the effect on distance and near vision. If vision is still not acceptable change the dominant eye to the next lowest ADD power. If the patient is wearing two low ADD lenses change the dominant eye to a sphere lens with a power equal to the spherical equivalent distance prescription.

Unacceptable Distance and Near Vision:

Determine the amount of additional plus and or minus over one or both eyes that is acceptable while checking the effect on distance and near vision. If additional plus and/or minus is not required change the lens power in the dominant eye to the next lowest ADD power and the lens power in the non-dominant eye to the next highest ADD power if applicable.

V. MULTIFOCAL-TORIC FITTING GUIDELINES

A. Presbyopic Needs Assessment & Patient Education

Multifocal contact lenses may produce compromise to vision under certain circumstances and the patient should understand that they might not find their vision acceptable in specific situations (i.e., reading a menu in a dim restaurant, driving at night in rainy foggy conditions, etc.). Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments. Occupational and environmental visual demands should be considered. If the patient requires critical visual acuity and stereopsis, it should be determined by trial whether this patient can function adequately with the VISTAKON® (narafilcon A-B) Multifocal-Toric Contact Lens. VISTAKON® (narafilcon A-B) Multifocal-Toric Contact Lens wear may not be optimal for such activities as:

1. visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
2. driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with the VISTAKON® (narafilcon A-B) Multifocal-Toric Contact Lens should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

B. VISTAKON® (narafilcon A-B) Multifocal-Toric Contact Lens Parameter Selection (Trial lens fitting)

A trial fitting is performed in the office to allow the patient to experience presbyopic correction with the VISTAKON® (narafilcon A-B) Multifocal-Toric Contact Lens and to determine the proper lens fit of the contact lenses (see Criteria of A Properly Fit Lens in the General Fitting Instructions). Since lens centration is important for multifocal toric lens performance, insert the trial lens with the steepest sagittal depth available.

C. VISTAKON® (narafilcon A-B) Multifocal-Toric Contact Lens Selection

It is important when prescribing the VISTAKON® (narafilcon A-B) Multifocal-Toric Contact Lens that you determine the stability, repeatability and drift angle of the lens axis so that you can prescribe the correct lens axis for your patient.

Initial Lens Power Selection

a) VISTAKON® (narafilcon A-B) Multifocal-Toric Contact Lenses come in the following ADD powers:

Lens "LOW" = "low" near ADD lens
Lens "MID" = "medium" near ADD lens
Lens "HIGH" = "high" near ADD lens

2. The cylinder power selected should be equal to the vertex adjusted cylinder power of the best corrected spectacle Rx.

Note: Any lens rotation is visually disturbing to the patient, so it's more practical to prescribe as weak a cylinder power as possible. A great deal of experience with patients has shown that it is possible to under-prescribe the minus cylinders near 180° ("with the rule") by as much as 30% and to under-prescribe minus cylinders near 90° ("against the rule") by as much as 20%. Therefore, if the cylinder correction is between two available cylinder powers, choose the less minus power.

Step 1	Determine: - Eye dominance (the methods described in MONOVISION SPHERE AND TORIC FITTING GUIDELINES may be used) - Spherical equivalent distance prescription (vertex corrected if necessary and rounded to less minus if between powers) - Near ADD
Step 2	Select the initial trial lens as follows: Initial Distance Power Selection For each eye, select the trial lens distance power that is closest to the patient's distance spherical equivalent. A patient with a spectacle Rx: (O.D.) = -3.00D -1.50D x 180, +1.50D ADD (O.S.) = -2.25D -1.50D x 170, +1.50D ADD Initial VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens distance power selection: (O.D.) = -3.00D -1.25D x 180 (O.S.) = -2.50D -1.25D x 170 Note: 1. Since the spectacle cylinder power is between two available VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens cylinder powers, choose the less minus contact lens cylinder power. Therefore, the initial VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens cylinder power selection = -1.25D 2. Choose the diagnostic lens with an axis closest to the patient's spectacle cylinder axis. Select the near power of the lens based on the patient's ADD range as follows: ADD: +0.75 to +1.25 use a "LOW" near ADD lens on each eye ADD: +1.50 to +1.75 use a "MID" near ADD lens on each eye ADD: +2.00 to +2.50 use a "HIGH" near ADD lens on each eye
Step 3	Allow the lens to settle for a minimum 10 minutes.
Step 4	- Assess distance and near vision binocularly and monocularly. - Demonstrate the vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate and near. - Make adjustments in power as necessary (see **Multifocal-Toric Troubleshooting** below). The use of hand-held trial lenses is recommended.

Step 5 **A. Locate the Orientation Marks**

To help determine the proper orientation of the toric lens, you'll find two primary marks about 1mm from the lens edge representing the vertical position on opposite ends of the lens at 6 and 12 o'clock (Fig. 1). Because of the lens' ballasting system, either mark can represent the vertical position – there is no "top" and "bottom" as in a prism-ballasted lens. You don't need to view both marks to assess orientation; simply look for the 6 o'clock mark as you would with a prism-ballasted lens.

Figure 1

You'll need a biomicroscope and a 1mm or 2mm parallelepiped to highlight the marks when the lens is fitted to the eye. There are a number of techniques you can use to improve the visibility of the 6 o'clock mark. With your parallelepiped and medium magnification (10x or 15x), slowly pan down the lens, looking just below the direct illumination at the retroilluminated area. Backlighting the mark this way should make them more visible. Sometimes manipulating the lower lid may be necessary to uncover the mark.

B. Observe Lens Rotation and Stability

Observe the position and stability of the "bottom" mark. It usually stabilizes at the 6 o'clock position. If it does, calculation of the lens power will be straightforward. The 6 o'clock position is not a "must", however; the absolute requirement is that the axis position be stable and repeatable.

The mark may stabilize somewhat left or right (drift) of the vertical meridian and still enable you to fit a toric lens for that eye, as long as the lens always returns to the same "drift axis" position after settling. The deviation can be compensated for in the final prescription. Your objective is to ensure that whatever position the initial lens assumes near 6 o'clock, this position must be stable and repeatable. With full eye movement or heavy blink, you may see the marks swing away, but they must return quickly to the original stable position. If the lens does not return quickly, you may need to select a different lens.

Assessing Rotation

Imagine the eye as a clock dial and every hour represents a 30° interval. If the orientation mark of the initial lens stabilizes somewhat left or right of the vertical position, the final lens will orient on the eye with the same deviation. You can use an axis reticule in the slit lamp or use a line-scribed lens in a spectacle trial frame to measure or estimate the "drift angle" of the cylinder axis.

To compensate for this "drift", measure or estimate the "drift" and round it off into 5° increments, then add or subtract it from the refractive axis to determine the correct cylinder axis. Use the LARS (Left Add, Right Subtract) method to determine which direction to compensate.

C. Final Lens Determination

When the diagnostic lens has its axis aligned in the same meridian as the patient's refractive axis, a spherocylindrical over-refraction may be performed and visual acuity determined. However, in the case of crossed axes, such as when the diagnostic lens axis is different from the spectacle cylinder axis, it is not advisable

Step 5 (cont.)

In fitting contact lenses, it is customary to prescribe the full power in the sphere. In the cylinder, however, any lens rotation is visually disturbing to the patient, so it's more practical to prescribe as weak a cylinder as possible. So, here is how to determine the final lens power.

For the Sphere:

If sphere alone or combined sphere and cylinder Rx ≥ +4.00D, compensate for vertex distance. If sphere alone or combined sphere and cylinder Rx ≤ +4.00D, vertex compensation is not necessary.

For the Cylinder:

Adjust the axis by the drift angle using LARS. Choose a cylinder that is ± 0.50D from the refractive cylinder.

Case Examples

Example 1

Manifest (spectacle) refraction:
O.D. -2.50 -1.25 x 180 20/20
O.S. -2.00 -1.00 x 180 20/20

Choose a diagnostic lens for each eye with an axis as close to 180° as possible. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate, based on the patient's initial response to the lens.

Check the orientation of the axis mark. If the bottom axis mark is in the 6 o'clock position on both eyes, choose the appropriate cylinder as listed previously.

Here is the Rx Prescribed Ordered:
O.D. -2.50 -1.25 x 180
O.S. -2.00 -0.75 x 180

Example 2

Manifest (spectacle) refraction:
O.D. -3.00 -1.00 x 90 20/20
O.S. -4.75 -2.00 x 90 20/20

Choose diagnostic lenses of -3.00 -0.75 x 90 for the right eye and -4.50 -1.75 x 90 for the left eye, the nearest lenses available to the spherical power and axis needed. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate. The orientation mark on the right lens rotates left from the 6 o'clock position by 10°.

The fitting indicates the following:

Right Eye

Compensate the 10° axis drift by adding it to the manifest refraction axis. Here is the Rx prescribed:
O.D. -3.00 -0.75 x 100

Left Eye

The lens on the left eye shows good centration, movement and a consistent tendency for the mark to drift right by 10° from the 6 o'clock position following a forced blink.

Since the manifest refraction called for a power of -4.75D, adjust for the vertex distance and reduce the sphere by 0.25D and prescribe the -1.75D cylinder. Compensate for the 10° axis drift by subtracting it from the manifest refraction. Here is the Rx prescribed:
O.S. -4.50 -1.75 x 80

C. If no adjustment was required and lens fit (see Criteria of A Properly Fit Lens in General Fitting Guidelines), axis orientation and rotational stability are acceptable, and the patient obtains acceptable visual performance, the trial lenses should be dispensed for up to one week of wear (see dispensing and follow up information in **PATIENT MANAGEMENT**).

D. If the patient does not obtain acceptable visual performance, please see the **Multifocal-Toric Troubleshooting** section.

D. Multifocal-Toric Troubleshooting:

Ensure that the lenses have been inserted properly. Some patients will exhibit poor vision from a lens that is inside out, but still report good comfort and the lens will exhibit good fit characteristics. If a lens is inside out, remove the lens and insert it properly. Allow the patient to adapt to the lens again before evaluating vision.

If lenses were inserted properly, ensure that axis orientation and rotational stability is acceptable. If the axis is not located at the 6 o'clock position, adjust the axis as previously mentioned in Step 5. If the axis is oriented properly and the rotational stability is acceptable but the patient has unacceptable vision, conduct a distance over-refraction to ensure the patient has the least minus most plus distance correction (i.e., ensure that the patient is not over-minused at distance). If the patient does not have the least minus most plus distance correction, adjust the prescription and reassess the visual performance.

If the patient does have the least minus most plus distance correction (i.e., is not over-minused at distance) but has unacceptable visual performance, please follow the suggestions below.

Unacceptable Near Vision:

Determine the amount of additional plus, or less minus, over one or both eyes that is acceptable while checking the effect on distance and near vision. If vision is still not acceptable change the non-dominant eye to the next highest ADD power.

Unacceptable Distance Vision:

Determine the amount of additional minus, or less plus, over one or both eyes that is acceptable while checking the effect on distance and near vision. If vision is still not acceptable change the dominant eye to the next lowest ADD power. If the patient is wearing two low ADD lenses change the dominant eye to a sphere lens with a power equal to the spherical equivalent distance prescription.

Unacceptable Distance and Near Vision:

Determine the amount of additional plus and/or minus over one or both eyes that is acceptable while checking the effect on distance and near vision. If additional plus and/or minus is not required change the lens power in the dominant eye to the next lowest ADD power and the lens power in the non-dominant eye to the next highest ADD power if applicable.

Prior to dispensing the lenses, check vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate and near. If distance and near vision are acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses, instructing the patient to return in one week for reassessment.

VI. MONOVISION (SPHERICAL AND TORIC FITTING GUIDELINES)

A. Patient Selection

Monovision Needs Assessment

For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than 1.00 D) in one eye may not be a good candidate for monovision correction with the VISTAKON® (narafilcon A) Contact Lens.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis), it should be determined by trial whether this patient can function adequately with monovision correction. Monovision contact lens wear may not be optimal for such activities as:

(a) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities: and

(b) driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with spectacles (multifocal, bifocal, trifocal, readers, progressives). Each patient should understand that Monovision, as well as other presbyopic alternatives, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments (e.g., reading a menu in a dim restaurant, driving at night in rainy/foggy conditions, etc.). During the fitting process, it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision and straight ahead and upward gaze that monovision contact lenses provide.

B. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following two methods for eye dominance can be used.

1. Ocular Preference Determination Methods

Method 1: Determine which eye is the "sighting eye". Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2: Determine which eye will accept the added power with the least reduction in vision. Place a hand-held trial lens equal to the spectacle near ADD in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near ADD lens over the right or left eye.

Other methods include the refractive error method and the visual demands method.

2. Refractive Error Method

For anisometropic correction, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

3. Visual Demands Method

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction, correct the eye on that side for near.

Example:
A secretary who places copy to the left side of the desk will function best with the near lens on the left eye.

C. Special Fitting Characteristics

1. Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may only require a distance lens.

Example:
A presbyopic emmetropic patient who requires a +1.75D ADD would have a +1.75D lens on the near eye and the other eye left without a lens.

A presbyopic patient requiring a +1.50D ADD who is -2.50D myopic in the right eye and -1.50D myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

2. Near ADD Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

3. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the General Fitting Instructions for base curve selection in this Package Insert.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine the distance correction and the near correction. Next determine the near ADD. With trial lenses of the proper power in place, observe the reaction to this mode of correction.

Allow the lenses to settle for about 20 minutes with the correct power lenses in place. Walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tests are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g., typewritten copy) at first and then graduate to newsprint and finally smaller type sizes.

After the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

4. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process, the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

Other Suggestions

The success of the monovision technique may be further improved by having your patient follow the suggestions below:

- Have a third contact lens (distance power) to use when critical distance viewing is needed.
- Have a third contact lens (near power) to use when critical near viewing is needed.

- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Monovision fitting can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of clear near vision and straight ahead and upward gaze with monovision.

The decision to fit a patient with a monovision correction is most appropriately left to the eye care professional in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the "VISTAKON® (narafilcon A B) Patient Instruction Guide".

PATIENT MANAGEMENT

Dispensing Visit

- **PROVIDE THE PATIENT WITH A COPY OF THE APPROPRIATE VISTAKON® PATIENT INSTRUCTION GUIDE. REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING SCHEDULE.**
- Schedule a follow-up examination.

Follow-up Examinations

- Follow-up care (necessary to ensure continued successful contact lens wear) should include routine periodic progress examinations, management of specific problems, if any, and a review with the patient of the wear schedule and handling procedures.

- Recommended Follow-up Examination Schedule for VISTAKON® Contact Lenses (complications and specific problems should be managed on an individual patient basis):

  1. One week from the initial lens dispensing to patient
  2. One month post-dispensing
  3. Every three to six months thereafter

Preferably, at the follow-up visits, lenses should be worn for at least six hours.

- Recommended Procedures for Follow-Up Visits:

  1. Solicit and record patient's symptoms, if any.

  2. Measure visual acuity monocularly and binocularly at distance and near with the contact lenses.

  3. Perform an over-refraction at distance and near to check for residual refractive error.

  4. With the biomicroscope, judge the lens fitting characteristics (as described in the General Fitting Guidelines) and evaluate the lens surface for deposits and damage.

5. Following lens removal, examine the cornea and conjunctiva with the biomicroscope and fluorescein (unless contraindicated).
    - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
    - The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear and/or a poorly fitting lens.
    - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

6. Periodically perform keratometry and spectacle refractions. The values should be recorded and compared to the baseline measurements.

If any observations are abnormal, use professional judgment to alleviate the problem and restore the eye to optimal conditions. If the criteria for successful fit are not satisfied during any follow-up examinations, repeat the patient's trial fitting procedure and refit the patient.

WEARING SCHEDULE

The wearing schedule should be determined by the Eye Care Professional. Patients tend to over wear the lenses initially. The Eye Care Professional should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the Eye Care Professional, are also extremely important.

DAILY DISPOSABLE WEAR (less than 24 hours, while awake)

- For daily disposable wear, VISTAKON® recommends that the VISTAKON® (narafilcon A B) Contact Lenses be discarded upon removal.

The maximum suggested wearing time for these lenses is:

Day	Hours
1	6-8
2	8-10
3	10-12
4	12-14
5 and after	all waking hours

LENS CARE DIRECTIONS

When lenses are dispensed, the Eye Care Professional should provide the patient with appropriate and adequate warnings and instructions in accordance with the individual patient's lens type and wearing schedule.

For VISTAKON® (narafilcon A B) Contact Lenses prescribed for daily wear single use only: The Eye Care Professional should review with patients that no cleaning or disinfection is needed. Patients should always dispose of lenses when they are removed and have replacement lenses or spectacles available.

CARE FOR A STICKING (NON-MOVING) LENS

If the lens sticks (stops moving), the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after a few minutes, the patient should immediately consult the Eye Care Professional.

EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with methyl ether cellulose. The plastic package is marked with base curve, diopter power, diameter, color (visibility tint noted on visibility tinted product only), lot number and expiration date. [ADD power, cylinder and axis will be included as appropriate].

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing VISTAKON® Contact Lenses or experienced with the lenses should be reported to:

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, FL 32256
Tel: 1-800-843-2020
www.acuvue.com

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PATIENT INSTRUCTION GUIDE
FOR SINGLE USE DAILY WEAR ONLY

VISTAKON® (narafilcon B) Contact Lenses (Spherical)
VISTAKON® (narafilcon B) Contact Lenses (Multifocal)
VISTAKON® (narafilcon B) Contact Lenses (Toric)
VISTAKON® (narafilcon B) Contact Lenses (Multifocal-Toric)

Visibility Tinted with UV Blocker

From the makers of ACUVUE® Brand Contact Lenses

VISTAKON

Vision Care, Inc.

153

TABLE OF CONTENTS

INTRODUCTION
INDICATIONS (USES) WEARING RESTRICTIONS
CONTRAINDICATIONS (REASONS NOT TO USE)
WARNINGS
PRECAUTIONS
ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)
PERSONAL CLEANLINESS FOR LENS HANDLING AND INSERTION
- Preparing the Lens for Wearing
- Opening the Multipack and Lens Package
- Handling the Lenses
- Placing the Lens on the Eye
- Centering the Lens
- Removing the Lens
- CARING FOR YOUR LENSES
- Basic Instructions
- Care for Sticking (Non-Moving) Lens
- Lens Case Cleaning and Maintenance
- Care for a Dried Out (Dehydrated) Lens
- Emergencies

INSTRUCTIONS FOR THE PRESBYOPIC PATIENT (MONOVISION & MULTIFOCAL)
WEARING AND APPOINTMENT SCHEDULES
PATIENT EYE CARE PROFESSIONAL INFORMATION
GLOSSARY OF TECHNICAL TERMS
SYMBOLS KEY

CAUTION: Federal U.S.A law restricts this device to sale by or on the order of a licensed practitioner.

INTRODUCTION

The information and instructions contained in this booklet apply only to the VISTAKON® (narafilcon A) Contact Lenses. Your contact lenses are intended to be used for daily wear single use only within the VISTAKON® planned lens replacement system.

Please refer to the Glossary of Technical Terms for definitions of medical/technical terminology used in this booklet. In addition, the Symbols Key provides an explanation of symbols that may appear on the lens packaging. After the wearing period prescribed by your Eye Care Professional, your contact lenses should be discarded and replaced with a new sterile pair. If you have any questions, always ask your Eye Care Professional. By replacing your contact lenses on a daily basis, lens deposits, which can affect vision and cause irritation and discomfort to the eye, have little chance to build up over time as with conventional lens wear. When you discard the lens, you dispose of potential deposit build-up problems. Your contact lenses are visibility tinted with a UV Blocker. An ultraviolet (UV) radiation absorbing ingredient is used to block UV radiation.

For your eye health, it is important that your contact lenses be worn only as prescribed by your Eye Care Professional. Your Eye Care Professional should be kept fully aware of your medical history. Your Eye Care Professional will tailor a total program of care based on your specific needs. He or she will review with you all instructions for lens handling and care, including how to safely and easily open the packaging. You will also be instructed on how to properly insert and remove lenses. This booklet will reinforce those instructions.

If you have any questions, always ask your Eye Care Professional.

INDICATIONS (USES) AND WEARING RESTRICTIONS

All VISTAKON® (narafilcon A) Soft Contact Lenses with UV Blocker help protect against transmission of harmful UV radiation to the cornea and into the eye.

The VISTAKON® (narafilcon A) Soft Contact Lens (spherical) is indicated 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® (narafilcon A) Multifocal Soft Contact Lens is indicated 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® (narafilcon A) Toric Soft Contact Lens is indicated 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® (narafilcon A) Multifocal-Toric Soft Contact Lens is indicated 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.

Your Eye Care Professional should prescribe the lenses for daily wear single use only. The Eye Care Professional will determine your wearing schedule. Your lenses are to be discarded upon removal.

Therefore, no cleaning or disinfecting is required.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the VISTAKON (narafilcon A) Contact Lens when any of the following conditions exist:

- Inflammation or infection in or around the eye or eyelids
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
- Any previously diagnosed condition that makes contact lens wear uncomfortable.
- Severe dry eye
- Reduced corneal sensitivity (corneal hypoesthesia)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or surrounding tissues (adnexa) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated

WARNINGS

What you should know about Contact Lens Wear

- Problems with contact lenses or lens care products could result in serious injury to the eye. Proper use and care of your contact lenses and lens care products, including lens cases, are essential for the safe use of these products.
- Eye problems, including a sore or lesion on the cornea (corneal ulcers) can develop rapidly and lead to loss of vision.
- The risk of an infected sore or lesion on the cornea (ulcerative keratitis) greater for people who wear extended wear contact lenses than for those who wear daily wear lenses.
- When daily wear users wear their lenses overnight (outside the approved use), the risk of infected sore or lesion on the cornea (ulcerative keratitis) is greater than among those who do not wear them while sleeping.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.
- The risk of ulcerative keratitis among contact lens users who smoke is greater than among non-smokers.
- If you experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, you should immediately remove your lenses and promptly contact your Eye Care Professional. It is recommended that you see your Eye Care Professional routinely as directed.

***WARNING: UV absorbing contact lenses are not substitutes for protective UV absorbing eyewear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.**

Note: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not

been done to demonstrate that wearing UV blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your Eye Care Professional for more information.

152

PRECAUTIONS

Handling Precautions:

• **DO NOT** use if the sterile blister package is opened or damaged.
• Before leaving the Eye Care Professional's office, you should be able to promptly remove the lenses or should have someone else available who can remove the lenses for you.
• **Always wash and rinse your hands before handling lenses**. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in your eyes or on your lenses. It is best to put on your lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
• **DO NOT** touch your contact lenses with your fingers or hands if they are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to your eye.
• **Carefully** follow the handling, insertion, removal and wearing instructions in this booklet and those prescribed by the Eye Care Professional.
• **Always** handle lenses carefully and avoid dropping them.
• **Never** use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour the lens and the packing solution into the hand.
• **Do not** touch the lens with your fingernails.

Lens Wearing Precautions:

• You should remove your lenses immediately if your eyes become red or irritated.
• **Never** wear your lenses beyond the period recommended by your Eye Care Professional.
• If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and **keep your eyes closed** until the spray has settled.
• **Avoid** all harmful or irritating vapors and fumes while wearing lenses.
• **Ask** your Eye Care Professional about wearing contact lenses during sporting activities, especially swimming and other water sports. Exposing contact lenses to water during swimming or while in a hot tub **may increase the risk of eye infection** from microorganisms.
• **Always throw away** lenses worn as prescribed by your Eye Care Professional.

Lens Care Precautions:

• The Eye Care Professionals should review with patients that no cleaning or disinfecting is needed with daily single use lenses. Patients should always dispose of lenses when they are removed and have replacement lenses or spectacles available.

Other Topics to discuss with Your Eye Care Professional:

• If you wear your contact lenses to correct presbyopia using monovision or if your contact lenses are Multifocal or Multifocal-Toric to correct presbyopia you **may not** achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered by our eye care professional in conjunction with you when selecting the most appropriate type of lens for you.

1-52

• **Always** contact your Eye Care Professional before using any medicine in your eyes.
• **Be aware** that certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers and those for motion sickness may cause dryness of the eye, increased lens awareness or blurred vision. Always inform your eye care professional if you experience any problems with your lenses while taking such medications. Depending on the severity, your eye care professional may prescribe the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.
• **Be aware** that if you use oral contraceptives, you could develop visual changes or changes in lens tolerance when using contact lenses.
• As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes.

Who should know that you are wearing Contact Lenses:

• **Inform** your doctor (Health Care Professional) about being a contact lens wearer.
• **Always** inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.

ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)

Be aware that the following problems may occur when wearing contact lenses:

- Your eyes may burn, sting and/or itch.
- There may be less comfort than when the lens was first placed on your eye.
- There may be a feeling of something in your eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers and corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.
- There may be excessive watering, unusual eye secretions or redness of your eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, sensitivity to light (photophobia) or dry eyes may also occur if your lenses are worn continuously or for too long a time.

You should conduct a simple 3-part self-examination at least once a day.

Ask yourself:
- How do the lenses feel on my eyes?
- How do my eyes look?
- Do I continue to see well?

If you report any problems, you should IMMEDIATELY REMOVE YOUR LENS.

If the discomfort or problem stops, you should look closely at the lens.

If the lens is in any way damaged, you SHOULD NOT put the lens back on your eye. You should discard the lens and insert a new fresh lens on your eye.

If your lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, you should dispose of the lens and insert a new fresh lens.

If the problem continues, you SHOULD NOT put the lens back on your eye but IMMEDIATELY CONSULT YOUR EYE CARE PROFESSIONAL.

When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. **Seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

PERSONAL CLEANLINESS FOR LENS HANDLING AND INSERTION

1. Prepare the Lens for Wearing

It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:

- Always wash your hands thoroughly with a mild soap, rinse completely and dry with a lint free towel before touching your lenses.
- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips, and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.

Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

2. Opening the Multipack and Lens Package

Multipack

Each multipack contains individually packaged lenses. Each lens comes in its own lens package designed specifically to maintain sterility. You may choose to keep your lenses inside the multipack for storage until you are ready to use them.

Lens Package

To open an individual lens package, follow these simple steps:

1. Shake the lens package and check to see that the lens is floating in the solution.

2. Peel back the foil closure to reveal the lens. By stabilizing the lens package on the table-top, you will minimize the possibility of a sudden splash.

Occasionally, a lens may adhere to the inside surface of the foil when opened, or to the plastic package itself. This will not affect the sterility of the lens. It is still perfectly safe to use. Carefully remove and inspect the lens following the handling instructions.

3. Handling the Lenses

- When you first get your lenses, be sure that you are able to put the lenses on and remove them before leaving your Eye Care Professional's office.
- Develop the habit of always working with the same lens first to avoid mix-ups.
- Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or tears. If the lens appears damaged, do not use it. Use the next lens in the multipack.

4. Placing the Lens on the Eye

Remember, always start with the same eye.

Once you have opened the lens package, removed, and examined the lens, follow these steps to apply the lens to your eye:

1. BE SURE THE LENS IS NOT INSIDE-OUT by following either of the following procedures:
   - Place the lens on the tip of your index finger and check its profile. The lens should assume a natural, curved, bowl-like shape. If the lens edges tend to point outward, the lens is inside out. Another method is to gently squeeze the lens between the thumb and forefinger. The edges should turn inward. If the lens is inside out, the edges will turn slightly outward.

OR

   - Place the lens on the tip of your index finger and, looking up at the lens, locate the numbers 123. 1-2-3 indicates correct orientation while a reverse of 1-2-3 indicates the lens is inside out. If the lens is inside out (reverse 1-2-3), invert the lens and locate the numbers again to confirm correct lens orientation.

2. Place the middle finger of the same hand close to your lower eyelashes and pull down the lower lid.

3. Use the index finger or middle finger of the other hand to lift the upper lid.

4. Place the lens on the eye.

5. Gently release the lids and blink. The lens will center automatically

6. Use the same technique when inserting the lens for your left eye

There are other methods of lens placement. If the above method is difficult for you, your Eye Care Professional will provide you with an alternate method.

After you have successfully inserted your lenses, you should ask yourself:
- Do I see well?
- How do the lenses feel on my eyes?
- How do my eyes look?

Note: If after placement of the lens, your vision is blurred, check for the following:

- The lens is not centered on the eye (see "Centering the Lens", next in this booklet).
- If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:

a. Cosmetics or oils on the lens. Dispose of the lens and insert a new fresh lens.
b. The lens is on the wrong eye.
c. The lens is inside out (it would also not be as comfortable as normal).

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your Eye Care Professional.

If a lens becomes less comfortable than when it was first inserted or if it is markedly uncomfortable upon insertion, remove the lens immediately and contact your Eye Care Professional.

If your examination shows any problems, IMMEDIATELY REMOVE YOUR LENSES AND CONTACT YOUR EYE CARE PROFESSIONAL.

5. Centering the Lens

A lens, which is on the cornea, will very rarely be displaced onto the white part of the eye during wear. This, however, can occur if insertion and removal procedures are not performed properly. To center a lens, follow either of these procedures:

a. Close your eyelids and gently massage the lens into place through the closed lids.

OR

b. Gently manipulate the off-centered lens onto the cornea while the eye is opened using finger pressure on the edge of the upper lid or lower lid.

6. Removing the Lens

Always remove the same lens first.

a. Wash, rinse and dry your hands thoroughly.

CAUTION: Always be sure the lens is on the cornea before attempting to remove it. Determine this by covering the other eye. If vision is blurred, the lens is either on the white part of the eye or it is not on the eye at all. To locate the lens, inspect the upper area of the eye by looking down into a mirror while pulling the upper lid up. Then inspect the lower area by pulling the lower lid down.

b. There are two recommended methods of lens removal: the Pinch Method and the Forefinger and Thumb Method. You should follow the method that is recommended by your Eye Care Professional.

Pinch Method:

1. Look up, slide the lens to the lower part of the eye using the forefinger.

2. Gently pinch the lens between the thumb and forefinger.

3. Remove the lens.

Forefinger and Thumb Method:

1. Place your hand or towel under your eye to catch the lens.

2. Place your forefinger on the center of the upper lid and your thumb on the center of the lower lid.

3. Press in and force a blink. The lens should fall onto your hand or the towel.

Once the lens is removed, simply follow the lens care directions recommended by your Eye Care Professional.

> **Note:** The lens may come out, but remain on the eyelid, finger or thumb.

4. Remove the other lens by following the same procedure.

5. Follow the required lens care procedures described under the heading, "Caring For Your Lenses (Cleaning, Rinsing, Disinfecting, Storage and Rewetting/Lubricating)".

> **Note**: If these methods of removing your lens are difficult for you, your Eye Care Professional will provide you with an alternate method.

CARING FOR YOUR LENSES

1. Basic Lens Care Instructions

If you require only vision correction, but will not or cannot always use the recommended care routine for your lenses, or are unable to put on and remove lenses or have someone available to place and remove them, you should not try to get and wear contact lenses.

- When you first get your lenses, be sure to put the lenses on and remove them while you are in your Eye Care Professional's office.
- Always wash, rinse, and dry your hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.
- Never rinse your lenses in water from the tap. There are two reasons for this:
  a. Tap water may contain impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
  b. You might lose your lens down the drain.

For Single Use Daily Wear:

Remember, there is no cleaning or disinfection needed with VISTAKON® (narafilcon A) Contact Lenses prescribed for daily single use wear only. Always dispose of lenses when they are removed and have replacement lenses or spectacles available.

2. Care For A Sticking (Non-moving) Lens

If a lens sticks (stops moving) on your eye, apply a few drops of the recommended lubricating solution. You should wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues, you should immediately consult your Eye Care Professional.

3. Lens Case Cleaning and Maintenance

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer and allowed to air dry. Lens cases should be replaced at regular intervals, as recommended by the lens case manufacturer or your Eye Care Professional.

4. Care For A Dried Out (Dehydrated) Lens

If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle. If this happens, dispose of the lens and use a new fresh one.

5. Emergencies

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

INSTRUCTIONS FOR THE PRESBYOPIC PATIENT (MONOVISION & MULTIFOCAL)

• You should be aware that, as with any type of lens correction, there are advantages and compromises to presbyopic contact lens correction. The benefit of clear near vision in straight ahead and upward gaze that is available with your contact lenses for monovision and multifocal correction may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to this. Symptoms, such as mild blurred vision and variable vision, may last for a brief period or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your chances for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations that are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first days of wearing your lens. It is recommended that you only drive with Monovision correction if you pass your state drivers license requirements with Monovision correction.

• Some presbyopic patients require supplemental spectacles to wear over your contact lenses for monovision or multifocal correction to provide the clearest vision for critical tasks. You should discuss this with your Eye Care Professional.

• Some presbyopic patients will never be fully comfortable functioning under low levels of lighting, such as driving at night. If this happens, you may want to discuss with your Eye Care Professional having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.

For monovision patients, if you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required. It is important that you follow your Eye Care Professional's suggestions for adaptation to presbyopic contact lens correction. You should discuss any concerns that you may have during and after the adaptation period

.

• The decision to be fit with Monovision or multifocal correction is most appropriately left to the Eye Care Professional, in conjunction with you, after carefully considering and discussing your needs.

WEARING AND APPOINTMENT SCHEDULE

Prescribed Wearing Schedule

Day	Wearing Time (Hours)
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	

Appointment Schedule
Your appointments are on:
Minimum number of hours lenses to be worn at time of appointment:
Month: Year:
Time: Day:

PATIENT/EYE CARE PROFESSIONAL INFORMATION

Next Appointment:
Date:
Dr:
Address:
Phone:

Day Date Hours Worn	Day Date Hours Worn
1	1
2	2
3	3
4	4
5	5
6	6
7	7

IMPORTANT: In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYE CARE PROFESSIONAL IMMEDIATELY.

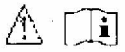
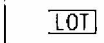
NOTES

Glossary of Technical Terms

Term	Definition
Adnexa	Tissues surrounding the eyeball
Ametropia	Abnormal vision requiring correction for proper focus
Anterior chamber	Internal portion of the eye, between the cornea and iris
Aphakic	An eye that does not have its natural lens (example: after cataract surgery)
Aspherical contact lens	A lens with a curve that is not round, but has different shapes across its surface
Astigmatism	A condition where the cornea is not equally curved in all parts of its surface. It is somewhat oval in shape, causing the visual image to be out of focus (blurred).
Conjunctiva	Membrane that lines the eyelids and the white part of the eye
Conjunctivitis	Inflammation of the conjunctiva
Cornea	Clear front part of the eye that covers the iris, pupil and anterior chamber
Corneal erosion	Wearing away of the surface of the cornea
Corneal staining	When a dye is put onto the eye and shows problems with the corneal surface
Corneal ulcer	A sore or lesion on the cornea
Disinfection	A process that kills harmful microorganisms (germs) which can cause serious eye infections
Edema	Swelling of tissue from excess fluid accumulation
Hydrophilic material	"Water loving" or water absorbing substance
Hyperopia	Farsightedness
Infiltrate	Redness
Iritis	Inflammation of the colored part of the eye (iris)
Inflammation	Swelling, redness, and pain
Monovision	A correction method for presbyopia (loss of reading vision) using contact lenses: one eye is fitted for distance, the other for near vision
Multifocal contact lens	A lens that can correct for both distance and near vision
Myopia	Nearsightedness
Neovascularization	Blood vessels growing into the cornea
Phakic	An eye that possesses its natural lens
Presbyopia	Condition in which as the lenses in the eyes lose some of their elasticity, as occurs with aging, they lose some of their ability to change focus for different distances. Usually becomes significant after age 45.
Spherical contact lens	A lens with a continuously rounded curve
Tarsal abnormalities	Problems with the eyelids
Toric contact lens	A lens with two different optical powers at right angles to each other for the correction of astigmatism
Toric-Multifocal contact lens	A lens that can correct for both distance and near vision with two different optical powers at right angles to each other for the correction of astigmatism
Ulcerative keratitis	An infected corneal ulcer
UV (Ultraviolet)	Light from the sun that can be harmful to the eye

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	See Instruction Leaflet
	Use By Date (expiration date)
	Batch Code
	Sterile Using Steam or Dry Heat
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
	UV Blocking
	Fee Paid for Waste Management
	Peel Back Foil
	Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner
C.T.	Center Thickness
	Visibility Tinted Lens Orientation Correct
	Visibility Tinted Lens Inside Out
CYL	Cylinder Power
AXIS	Axis
LOW	"Low" near ADD
MID	"Medium" near ADD
HIGH	"High" near ADD

VISTAKON

Vision Care, Inc.
Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, Florida 32256
1-800-843-2020
www.acuvue.com

©JJVCI 2009
AT 11 09 01

Date

K 100349

Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

Guidance for Industry and FDA Staff

Format for Traditional and Abbreviated 510(k)s

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm

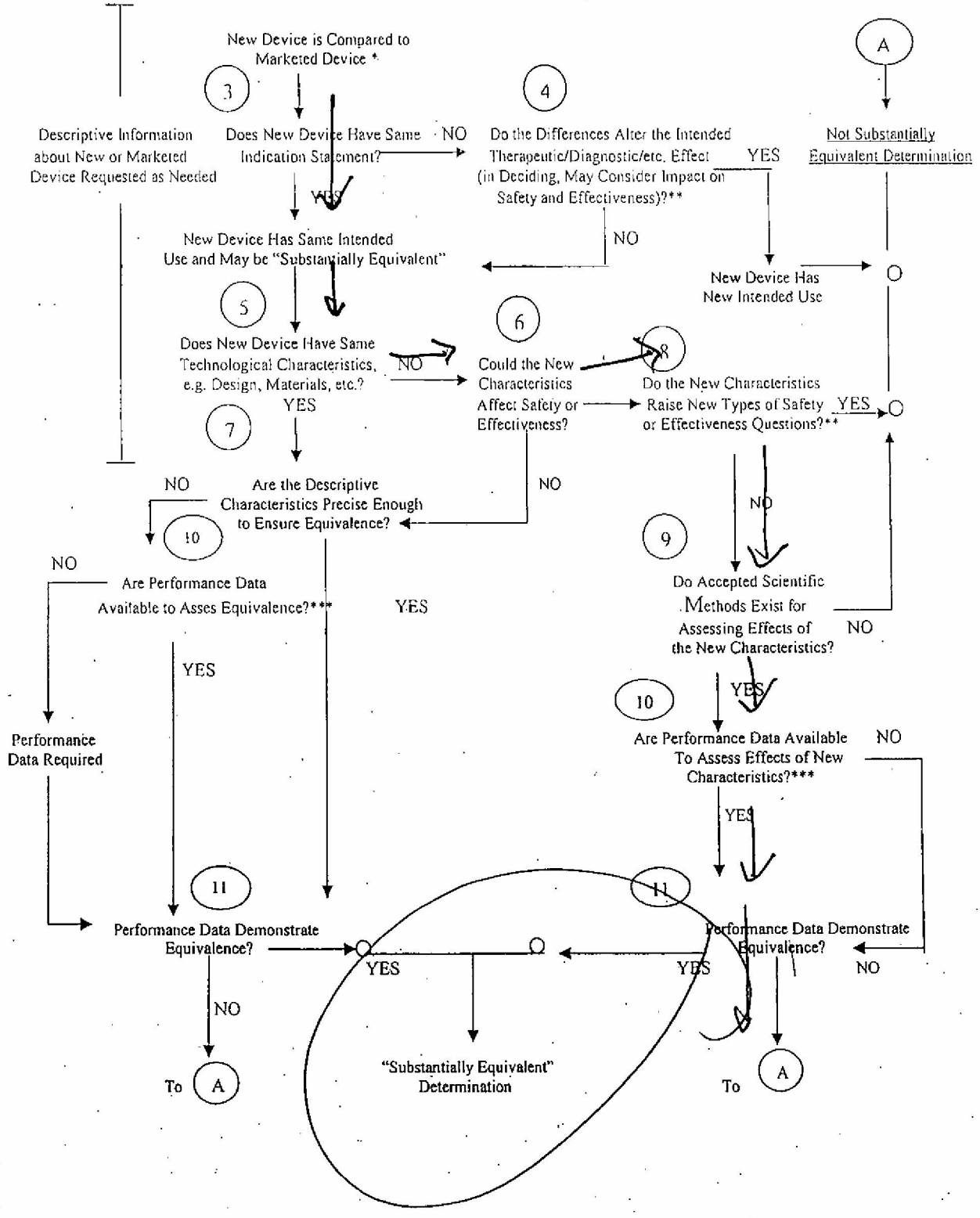
Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFeeandModernizationAct/ucm155274.htm	✓		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf	✓		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	✓		
Indications for Use Statement	Device Advice " Content of a 510(k)" Section D http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080275.htm	✓		
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm	✓		
Truthful and Accuracy Statement	Device Advice " Content of a 510(k)" Section G http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm	✓		
Class III Summary and Certification	Class III Summary and Certification Form http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm			✓
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf Financial Disclosure by Clinical Investigators http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm	✓		

Title	Related Information	Present	Inadequate	N/A
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/default.htm See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)			✓
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	✓		
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	✓		
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf	✓		
FORM FDA 3654, *Standards Data Report for 510(k)s - http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf*	**Standards Data Report Form – Form 3654** 1: No standard used - **No Standards Form Required** 2: Declaration of Conformity – **Yes Standards Form Required** 3: Standard but no declaration – **Yes Standards Form Required**	✓		
Kit Certification	Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080213.htm			✓

Last Updated: 9/3/08 – Brandi Stuart

Title	Related Information	Present	Inadequate	N/A
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073752.htm FDA Standards program http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142706.htm	✓		
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	✓		
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	✓		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm	✓		
Proposed Labeling	Device Advice " Content of a 510(k)" Section H http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm	✓		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.htm	✓		
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm	✓		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm			✓

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Johnson & Johnson K100349/S001

Vision Care, Inc.

May 4, 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: K100349/A001 Additional Information requested in Letter dated April 26, 2010

Dear Sir/Madam(s):

Johnson & Johnson Vision Care, Inc., is pleased to submit this amendment in response to the request for additional information dated April 26, 2010.

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

FDA CDRH DMC
MAY - 5 2010
Received

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
May 4, 2010	MD6047400-956733	K100349/A001

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☒ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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

FORM FDA 3514 (3/08)

PSC Graphics (301) 443-1090 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify):*

Change in lens material.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LPL	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

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) (narafilcon A) Contact Lens	1	Johnson & Johnson Vision Care, Inc.
2	K962804	2	VISTAKON(R) (etafilcon 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) (narafilcon 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	C.F.R. Section *(if applicable)*	Device Class
LPL	21 CFR 886.5925	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Ophthalmic Devices

Indications *(from labeling)*

Provided on the following page.

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 1057985	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ 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	

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 9617710	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ 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	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ 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	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

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.

Table of Contents

Section	Page
CDRH Cover Sheet	1
Table of Contents	6
Cover Letter	7
Item 1	8
Item 2	9
Item 3	10
Item 4	12
Item 5	14
Item 6	15
Item 7	16
Item 8	17
Item 9	18
Item 10	19
Attachment 1: Indications for Use Statement	22
Attachment 2: 510(k) Summary	23
Attachment 3: Package Insert and Patient Management Guide	24
Attachment 4: Patient Instruction Guide	25
Attachment 5: Manufacturing Flow Chart	26

Johnson & Johnson

Vision Care, Inc.

May 4, 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: K100349/A001 Additional Information requested in Letter dated April 26, 2010

Dear Sir/Madam(s):

Johnson & Johnson Vision Care, Inc., is pleased to submit this amendment in response to the request for additional information dated April 26, 2010.

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

Item 1

Question

You provide indications for use for the multifocal, toric, and multifocal toric lens designs; however you do not describe the ADD power ranges. Please revise the indications for use to include the ADD power and cylinder ranges for the multifocal, toric, and multifocal toric lenses and provide modified labeling, indications for use form and a 510(k) summary that includes the revised indications.

Response

The ADD power ranges have been added to the multifocal and multifocal-toric indications for use. The cylinder powers were included in the initial indications for use. The revised indications are provided below with the changes indicated in red text.

Design	Indication
Multifocal	The VISTAKON® (narafilcon 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.
Toric	The VISTAKON® (narafilcon 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.
Multifocal -Toric	The VISTAKON® (narafilcon 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.

As requested, the following documents are provided as Attachments:

- **Attachment 1**: Indications for Use Statement
- **Attachment 2**: 510(k) Summary
- **Attachment 3**: Package Insert and Fitting and Patient Management Guide
- **Attachment 4:** Patient Instruction Guide

Item 2

Question

(b)(4)

Response

Item 3

Question

Response

(b)(4)

Continued on next page

Item 3, Continued

(b)(4)

Item 4

Question

Response

(b)(4)

Continued on next page

Item 4, Continued

Response (continued)

(b)(4)

Item 5

Question

Response

(b)(4)

Item 6

Question

Response

(b)(4)

Item 7

Question

Response

(b)(4)

Item 8

Question

Response

(b)(4)

Item 9

Question

(b)(4)

Response

Item 10

Question

(b)(4)

Response

Continued on next page

[1] Begley, C. G., et al. 2000. "Responses of Contact Lens Wearers to a Dry Eye Survey." *Optometry and Vision Science* 77:40-6

[2] Guillon, M. and C. Maissa. 2005. "Dry Eye Symptomatology of Soft Contact Lens Wearers and Nonwearers." Optometry and Vision Science 82:829-834.

Item 10, Continued

(b)(4)

Continued on next page

Item 10, Continued

(b)(4)

Attachment 1

Contents The updated Indications for Use Statement is provided in this Attachment.

Indications for Use Statement

510(k) Number (if known):

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

Indications for Use:

The VISTAKON® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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)

Attachment 2

Contents The updated 510(k) Summary is provided in this Attachment.

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

Indication, Wear Schedule

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

Continued on next page

510(k) Summary, Continued

Description of Device

- The VISTAKON® (narafilcon 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® (narafilcon 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® (narafilcon 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% narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon 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® (narafilcon B) Contact Lenses are compared to the characteristics of the predicate device, VISTAKON® (narafilcon A) Contact Lens, in the following tables.

Material Comparison		
	Predicate Device	**Subject Device**
Product Name	VISTAKON® (narafilcon A) Contact Lens	VISTAKON® (narafilcon B) Contact Lens
Material USAN Name	narafilcon A	narafilcon 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® (narafilcon A) Contact Lens – K073485		**Subject Device** VISTAKON® (narafilcon 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: $10^{-11}(cm^2/sec)(ml\ O_2/ml \times mmHg)$

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® (narafilcon 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® (narafilcon 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.

Attachment 3

Contents

The updated Package Insert and Fitting and Patient Management Guide is provided in this Attachment.

PACKAGE INSERT
&
FITTING AND PATIENT MANAGEMENT GUIDE

IMPORTANT: Please read carefully and keep this information for future use.

This Package Insert is intended for the Eye Care Professional, but should be made available to patients upon request. The Eye Care Professional should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

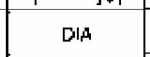
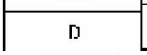
VISTAKON® (narafilcon B) Contact Lenses (Spherical)
VISTAKON® (narafilcon B) Contact Lenses (Multifocal)
VISTAKON® (narafilcon B) Contact Lenses (Toric)
VISTAKON® (narafilcon B) Contact Lenses (Multifocal-Toric)

Visibility Tinted with UV Blocker
For Single Use Daily Wear Only

VISTAKON® (narafilcon B) Contact Lenses (Spherical); VISTAKON® (narafilcon B) Multifocal Contact Lenses; VISTAKON® (narafilcon B) Toric Contact Lenses VISTAKON® (narafilcon B) Multifocal-Toric Contact Lenses; Soft (hydrophilic) Contact Lenses- Visibility Tinted with UV Blocker for Daily Wear Single Use only.

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	See Instruction Leaflet
	Use By Date (expiration date)
	Batch Code
	Sterile Using Steam or Dry Heat
	Diameter
	Base Curve
	Diopter (lens power)
	UV Blocking
	Fee Paid for Waste Management
	Peel Back Foil
	Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner
	Center Thickness
	Visibility Tinted Lens Orientation Correct Visibility Tinted Lens Inside Out
	Cylinder Power Axis
LOW	"Low" near ADD
MID	"Medium" near ADD
HIGH	"High" near ADD

Spherical Lenses For:
Myopia, Hyperopia, Phakic or Aphakic

Multifocal Lenses For:
Presbyopia, Phakic or Aphakic

Toric Lenses For:
Myopic Astigmatism, Hyperopic Astigmatism, Mixed Astigmatism, Phakic or Aphakic

Multifocal-Toric Lenses For:
Presbyopic Astigmatism , Phakic or Aphakic

CAUTION: Federal U.S.A law restricts this device to sale by or on the order of a licensed practitioner.

DESCRIPTION

The VISTAKON® (narafilcon B) Soft (hydrophilic) Contact Lenses are available as a Spherical, Multifocal, Toric or a Multifocal-Toric lens. The lenses are made of a silicone hydrogel material containing an internal wetting agent with visibility tinted UV absorbing monomer. The VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV Blocker is tinted blue using Reactive Blue Dye #4 to make the lenses 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 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

Lens Properties:

- **Specific Gravity: 1.07**
- **Refractive Index: 1.41**
- **Light Transmittance: 85% minimum**
- **Surface Character: Hydrophilic**
- **Water Content: 48%**
- **Oxygen Permeability:**

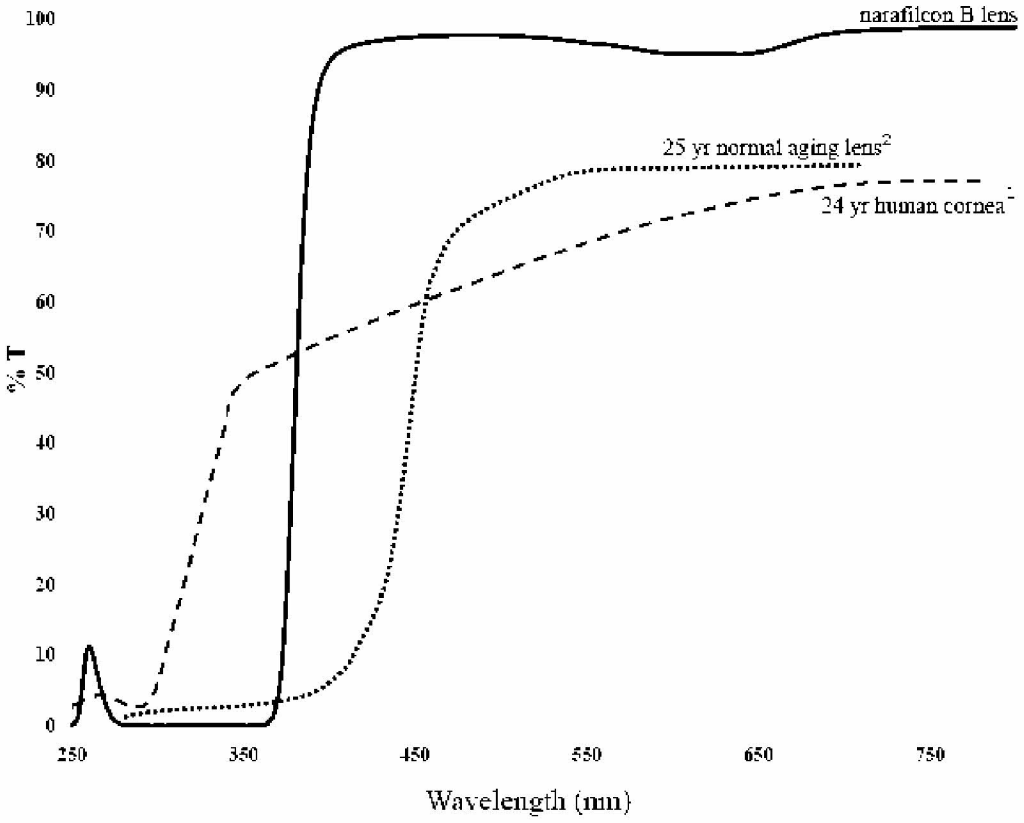
VALUE	**METHOD**
55×10^{-11} (cm^2/sec) (ml O2/ml x mm Hg) at 35°C	Polarographic edge and boundary corrected

Lens Parameters:

The VISTAKON® (narafilcon B) Contact Lenses are a hemispherical and/or hemitoric shell available within the following dimensions:

Diameter Range:	12.0mm to 15.0mm		
Center Thickness:	Low minus lens – (0.085mm)		
	Plus lens – varies with power (e.g., +3.00D: 0.170mm)		
Base Curve Range:	7.80mm to 10.00mm		
Power Range:			
	Spherical Power:	Daily Wear	-20.00D to +20.00D
	Multifocal ADD Powers:		+0.25D to +4.00D
	Multifocal-Toric ADD Powers:		+0.25D to +4.00D
	Cylinder Power:		-0.25D to -10.00D
	Axis:		2.5 ° to 180 °

Transmittance Curves
VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV Blocker, 24 yr. old human cornea and 25 yr. old human crystalline lens



* The data was obtained from measurements taken through the central 3-5mm portion for the thinnest marketed lens (-1.00D lens, 0.085mm center thickness).

1. Lerman, S., Radiant Energy and the eye, MacMillan, New York, 1980, p.58, figure 2-21
2. Waxler, M. Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.10, figure 5

WARNING: UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.

ACTIONS
In its hydrated state, the VISTAKON® (narafilcon B) Contact Lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

The transmittance characteristics are less than 1% in the UVB range of 280nm to 315nm and less than 10% in the UVA range of 316nm to 380nm for the entire power range.

Note: Long term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV blocking contact lenses help provide

protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your Eye Care Professional for more information.

INDICATIONS (USES)

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

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

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

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

Eye Care Professionals should prescribe the lenses for daily wear single use only (see "Wearing Schedule"). The lenses are to be discarded upon removal. Therefore, no cleaning or disinfection is required.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the VISTAKON (narafilcon B) Contact Lens when any of the following conditions exist:

- Inflammation or infection in or around the eye or eyelids
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
- Any previously diagnosed condition that makes contact lens wear uncomfortable.
- Severe dry eye
- Reduced corneal sensitivity (corneal hypoesthesia)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or surrounding tissues (adnexa) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated

WARNINGS
Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products, including lens cases, are essential for the safe use of these products
- Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- Studies have shown that the risk of ulcerative keratitis is greater for extended wear contact lens users than for daily wear users[1].
- When daily wear users wear their lenses overnight (outside the approved indication), the risk of ulcerative keratitis is greater than among those who do not wear them overnight.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.
- Studies have shown that the risk of ulcerative keratitis among contact lens users who smoke is greater than among non-smokers.

If patients experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, they should be instructed to immediately remove their lenses and promptly contact their Eye Care Professional. It is recommended that contact lens wearers see their Eye Care Professional routinely as directed.

[1] New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

PRECAUTIONS

Special Precautions for Eye Care Professionals:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the Eye Care Professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness and optic zone diameter.

  The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing Eye Care Professional.

- Patients who wear the VISTAKON® (narafilcon B) Contact Lenses to correct presbyopia using Monovision or patients who use the VISTAKON® Multifocal Contact Lenses or the VISTAKON® Multifocal-Toric Contact Lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Eye Care Professionals should instruct the patient to remove the lenses immediately if the eyes become red or irritated.

Eye Care Professionals should carefully instruct lens wear patients about the following care regimen and safety precautions:

Handling Precautions:

- Before leaving the Eye Care Professional's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.
- **DO NOT** use if the sterile blister package is opened or damaged.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, and wearing instructions in the "Patient Instruction Guide" for the VISTAKON® Contact Lens and those prescribed by the Eye Care Professional.
- Always handle lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens and the packing solution into the hand.
- Do not touch the lens with fingernails.

Lens Wearing Precautions:

- If the lens sticks (stops moving) on the eye, follow the recommended directions in "Care for a Sticking Lens". The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her Eye Care Professional.
- Never wear lenses beyond the period recommended by the Eye Care Professional.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the Eye Care Professional about wearing lenses during sporting activities, especially swimming and other water sports. Exposing contact lenses to water during swimming or while in a hot tub may increase the risk of eye infection from microorganisms.
- Always discard lenses worn as prescribed by the Eye Care Professional.

Lens Care Precautions:
The patient should be informed that no cleaning or disinfection is needed with daily wear single use only lenses. Patients should always dispose of lenses when removed and have replacement lenses or spectacles available.

Other Topics to Discuss with Patients:
- Always contact the Eye Care Professional before using any medicine in the eyes.
- Certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers and those for motion sickness, may cause dryness of the eye, increased lens awareness or blurred vision. Should such conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

Who Should Know That the Patient is Wearing Contact Lenses?
- Inform the doctor (Health Care Professional) about being a contact lens wearer.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

ADVERSE REACTIONS
The patient should be informed that the following problems may occur when wearing contact lenses:

- The eye may burn, sting and/or itch.
- There may be less comfort than when the lens was first placed on the eye.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers and corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.
- There may be excessive watering, unusual eye secretions, or redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, photo-phobia, or dry eyes may also occur if the lenses are worn continuously or for too long a time.

The patient should be instructed to conduct a simple 3-part self-examination at least once a day. They should ask themselves:

- How do the lenses feel on my eyes?
- How do my eyes look?
- Have I noticed a change in my vision?

If the patient reports any problems, he or she should be instructed to IMMEDIATELY REMOVE THE LENS.

If the discomfort or problem stops, the patient should then look closely at the lens.

If the lens is in any way damaged, the patient SHOULD NOT put the lens back on the eye. The patient should discard the lens and apply a new fresh lens on the eye.

If the lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, he or she should be instructed to dispose of the lens and apply a new fresh lens.

If the problem continues, the patient SHOULD NOT put the lens back on the eye but IMMEDIATELY CONSULT HIS OR HER EYE CARE PROFESSIONAL.

The patient should be instructed NOT to use a new lens as self-treatment for the problem.

The patient should be advised that when any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. He or she should be instructed to seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING GUIDELINES

I. GENERAL FITTING INSTRUCTIONS

VISTAKON® (narafilcon B) Contact Lens (Spherical)
VISTAKON® (narafilcon B) Contact Lens (Toric)
VISTAKON® (narafilcon B) Contact Lens (Multifocal)
VISTAKON® (narafilcon B) Contact Lens (Multifocal-Toric)

A. Patient Selection:

Patients selected to wear VISTAKON® (narafilcon B) Contact Lenses should be chosen based on:

- Motivation to wear lenses
- Ability to follow instructions regarding lens wear care
- General health
- Ability to adequately handle and care for the lenses
- Ability to understand the risk and benefits of lens wear.

Patients who do not meet the above criteria should not be provided with contact lenses.

B. Pre-fitting Examination

Initial evaluation of the patient should begin with a thorough case history to determine if there are any contraindications to contact lens wear. During the case history, the patient's visual needs and expectations should be determined as well as an assessment of their overall ocular, physical, and mental health.

Preceding the initial selection of trial contact lenses, a comprehensive ocular evaluation should be performed that includes, but is not limited to, the measurement of distance and near visual acuity, distance and near refractive prescription (including determining the preferred reading distance for presbyopes), keratometry and biomicroscopic evaluation.

Based on this evaluation, if it is determined that the patient is eligible to wear VISTAKON® (narafilcon B) Contact Lenses, the Eye Care Professional should proceed to the appropriate lens fitting instruction outlined below.

C. Initial Power Determination

A spectacle refraction should be performed to establish the patient's baseline refractive status and to guide in the selection of the appropriate lens power. Remember to compensate for vertex distance if the refraction is greater than ±4.00 D.

D. Base Curve Selection (Trial Lens Fitting)

For the VISTAKON® (narafilcon B) Spherical and Toric lenses, the 8.5mm/14.2mm Contact Lens should be selected for myopic patients regardless of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status. For the VISTAKON® (narafilcon B) Multifocal and Multifocal-Toric Contact Lenses, the initial lens should be selected from the currently available base curves.

A VISTAKON® (narafilcon B) trial lens should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses.

1. Criteria of a Properly Fit Lens

   A properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement to provide tear exchange under the contact lens with the blink and be comfortable. The lens should move freely when manipulated digitally with the lower lid, and then return to its properly centered position when released. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

2. Criteria of a Flat Fitting Lens

   A flat fitting lens may exhibit one or more of the following characteristics: decentration, incomplete corneal coverage (i.e., limbal exposure), excessive movement with the blink and/or edge standoff. If the VISTAKON® (narafilcon B) Contact Lens is judged to be flat fitting, it should not be dispensed to the patient.

3. Criteria of a Steep Fitting Lens

   A steep fitting lens may exhibit one or more of the following characteristics: insufficient movement with the blink, conjunctival indentation and resistance when pushing the lens up digitally with the lower lid. If the VISTAKON® (narafilcon B) Contact Lens is judged to be steep fitting, it should not be dispensed to the patient.

If the initial VISTAKON® (narafilcon B) base curve is judged to be flat or steep fitting, the alternate base curve, if available, should be trial fit and evaluated after the patient has adjusted to the lens. The lens should move freely when manipulated digitally with lower lid, and then return to a properly centered position when released. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

II. SPHERICAL LENS FITTING GUIDELINES

A spherical over-refraction should be performed to determine the final lens power after the lens fit is judged acceptable. The spherical over-refraction should be combined with the trial lens power to determine the final lens prescription. The patient should experience good visual acuity with the correct lens power unless there is excessive residual astigmatism.

Example 1:		
Diagnostic lens:		-2.00 D
	Spherical over-refraction	-0.25 D
	Final lens power:	-2.25 D

Example 2:		
Diagnostic lens:		-2.00 D
	Spherical over-refraction	+0.25 D
	Final lens power:	-1.75 D

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow up information in **PATIENT MANAGEMENT**).

III. TORIC FITTING GUIDELINES

Although most aspects of the fitting procedure are identical for all types of soft contact lenses, including torics, there are some additional steps and/or rules to follow to assure the proper fit of toric lenses.

The only new steps you must follow in prescribing the VISTAKON® (narafilcon B) Toric Contact Lenses are that you must determine the stability, repeatability and drift angle of the lens axis so that you can prescribe the correct lens axis for your patient.

A. How to Determine Lens Cylinder and Axis Orientation for VISTAKON® Toric Lenses

1. Locate the Orientation Marks

To help determine the proper orientation of the toric lens, you'll find two primary marks about 1mm from the lens edge representing the vertical position on opposite ends of the lens at 6 and 12 o'clock (Fig. 1). Because of the lens' ballasting system, either mark can represent the vertical position – there is no "top" and "bottom" as in a prism-ballasted lens. You don't need to view both marks to assess orientation; simply look for the 6 o'clock mark as you would with a prism-ballasted lens.

Figure 1

You'll need a biomicroscope and a 1mm or 2mm parallelepiped to highlight the marks when the lens is fitted to the eye. There are a number of techniques you can use to improve the visibility of the 6 o'clock mark. With your parallelepiped and medium magnification (10x or 15x), slowly pan down the lens, looking just below the direct illumination at the retroilluminated area. Backlighting the mark this way should make them more visible. Sometimes manipulating the lower lid may be necessary to uncover the mark.

2. Observe Lens Rotation and Stability

Observe the position and stability of the "bottom" mark. It usually stabilizes at the 6 o'clock position. If it does, calculation of the lens power will be straightforward. The 6 o'clock position is not a "must", however; the absolute requirement is that the axis position be stable and repeatable.

The mark may stabilize somewhat left or right (drift) of the vertical meridian and still enable you to fit a toric lens for that eye, as long as the lens always returns to the same "drift axis" position after settling. The deviation can be compensated for in the final prescription. Your objective is to ensure that whatever position the initial lens assumes near 6 o'clock, this position must be stable and repeatable. With full eye movement or heavy blink, you may see the marks swing away, but they must return quickly to the original stable position. If the lens does not return quickly, you may need to select a different lens.

Assessing Rotation

Imagine the eye as a clock dial and every hour represents a 30° interval. If the orientation mark of the initial lens stabilizes somewhat left or right of the vertical position, the final lens will orient on the eye with the same deviation. You can use an axis reticule in the slit lamp or

use a line-scribed lens in a spectacle trial frame to measure or estimate the "drift angle" of the cylinder axis.

To compensate for this "drift", measure or estimate the "drift", then add or subtract it from the refractive axis to determine the correct cylinder axis. Use the LARS (Left Add, Right Subtract) method to determine which direction to compensate.

B. How to determine the Final Lens Power for VISTAKON® (narafilcon B) Toric Contact Lens

When the diagnostic lens has its axis aligned in the same meridian as the patient's refractive axis, a spherocylindrical over-refraction may be performed and visual acuity determined. However, in the case of crossed axes, such as when the diagnostic lens axis is different from the patient's refractive axis, it is not advisable to over-refract because of the difficulty in computing the resultant power.

In fitting contact lenses, it is customary to prescribe the full power in the sphere. In the cylinder, however, any lens rotation is visually disturbing to the patient, so it's more practical to prescribe as weak a cylinder as possible. So, here is how to determine the final lens power.

For the Sphere:

If sphere alone or combined sphere and cylinder Rx $\geq \pm 4.00$D, compensate for vertex distance. If sphere alone or combined sphere and cylinder Rx $\leq \pm 4.00$D, vertex compensation is not necessary.

For the Cylinder:

Adjust the axis by the drift angle using LARS. Choose a cylinder that is ≤ 0.25D from the refractive cylinder.

Case Examples

Example 1
Manifest (spectacle) refraction:
O.D. –2.50 -1.25 x 180 20/20
O.S. –2.00 -1.00 x 180 20/20

Choose a diagnostic lens for each eye with an axis as close to 180° as possible. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate, based on the patient's initial response to the lens.

Check the orientation of the axis mark. If the bottom axis mark is in the 6 o'clock position on both eyes, choose the appropriate cylinder as listed previously.

Here is the Rx Prescribed/Ordered:
O.D. -2.50 -1.25 x 180
O.S. –2.00 -0.75 x 180

Example 2
Manifest (spectacle) refraction:
O.D. –3.00 -1.00 x 90 20/20
O.S. –4.75 -2.00 x 90 20/20

Choose diagnostic lenses of –3.00 –0.75 x 90 for the right eye and –4.50 -1.75 x 90 for the left eye, the nearest lenses available to the spherical power and axis needed. Place the lens on each eye

and allow a minimum of 3 minutes for it to equilibrate. The orientation mark on the right lens rotates left from the 6 o'clock position by 10°.

The fitting indicates the following:

Right Eye

Compensate the 10° axis drift by adding it to the manifest refraction axis. Here is the Rx prescribed:
O.D. –3.00 –0.75 x 100

Left Eye

The lens on the left eye shows good centration, movement and a consistent tendency for the mark to drift right by 10° from the 6 o'clock position following a forced blink.

Since the manifest refraction called for a power of –4.75D, adjust for the vertex distance and reduce the sphere by 0.25D and prescribe the –1.75D cylinder. Compensate for the 10° axis drift by subtracting it from the manifest refraction. Here is the Rx prescribed:
O.S. –4.50 –1.75 x 80

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow up information in **PATIENT MANAGEMENT**).

IV. MULTIFOCAL FITTING GUIDELINES

A. Presbyopic Needs Assessment & Patient Education

Multifocal contact lenses may produce compromise to vision under certain circumstances and the patient should understand that they might not find their vision acceptable in specific situations (i.e., reading a menu in a dim restaurant, driving at night in rainy/foggy conditions, etc.). Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments. Occupational and environmental visual demands should be considered. If the patient requires critical visual acuity and stereopsis, it should be determined by trial whether this patient can function adequately with the VISTAKON® (narafilcon B) Multifocal Contact Lens. VISTAKON® (narafilcon B) Multifocal Contact Lens wear may not be optimal for such activities as:

1. visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
2. driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with the VISTAKON® (narafilcon B) Multifocal Contact Lens should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

VISTAKON® (narafilcon B) Multifocal Contact Lenses are not recommended for patients who have –1.00 D or greater of refractive cylinder as this level of uncorrected cylinder may lead to additional visual compromise.

VISTAKON® (narafilcon B) Multifocal Contact Lenses come in the following ADD powers:
Lens "LOW" ="low" near ADD lens
Lens "MID" = "medium" near ADD lens
Lens "HIGH" = "high" near ADD lens

VISTAKON® (narafilcon B) Multifocal Contact Lenses Fitting Instructions

Step 1	Determine: - Eye dominance (the methods described in MONOVISION SPHERE AND TORIC FITTING GUIDELINES may be used) - Spherical equivalent distance prescription (vertex corrected if necessary and rounded to less minus if between powers) - Near ADD
Step 2	Select the initial trial lens as follows: - For each eye select the trial lens distance power that is closest to the patient's distance spherical equivalent. Select the near power of the lens based on the patients ADD range as follows: ADD: +0.75 to +1.25 use a "LOW" near ADD lens on each eye ADD: +1.50 to +1.75 use a "MID" near ADD lens on each eye ADD: +2.00 to+2.50 use a "HIGH" near ADD lens on each eye
Step 3	Allow the lens to settle for a minimum 10 minutes.
Step 4	- Assess distance and near vision binocularly and monocularly. - Demonstrate the vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate and near. - Make adjustments in power as necessary (see **Multifocal Troubleshooting** below). The use of hand-held trial lenses is recommended. - If distance and near vision are acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow up information in PATIENT MANAGEMENT).

C. Multifocal Troubleshooting

Unacceptable Near Vision:

Determine the amount of additional plus, or less minus, over one or both eyes that is acceptable while checking the effect on distance and near vision. If vision is still not acceptable change the non-dominant eye to the next highest ADD power.

Unacceptable Distance Vision:

Determine the amount of additional minus, or less plus, over one or both eyes that is acceptable while checking the effect on distance and near vision. If vision is still not acceptable change the dominant eye to the next lowest ADD power. If the patient is wearing two low ADD lenses change the dominant eye to a sphere lens with a power equal to the spherical equivalent distance prescription.

Unacceptable Distance and Near Vision:

Determine the amount of additional plus and/or minus over one or both eyes that is acceptable while checking the effect on distance and near vision. If additional plus and/or minus is not required change the lens power in the dominant eye to the next lowest ADD power and the lens power in the non-dominant eye to the next highest ADD power if applicable.

V. MULTIFOCAL-TORIC FITTING GUIDELINES

A. Presbyopic Needs Assessment & Patient Education

Multifocal contact lenses may produce compromise to vision under certain circumstances and the patient should understand that they might not find their vision acceptable in specific situations (i.e., reading a menu in a dim restaurant, driving at night in rainy/foggy conditions, etc.). Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments. Occupational and environmental visual demands should be considered. If the patient requires critical visual acuity and stereopsis, it should be determined by trial whether this patient can function adequately with the VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens. VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens wear may not be optimal for such activities as:

1. visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
2. driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with the VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

B. VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens Parameter Selection (Trial lens fitting)

A trial fitting is performed in the office to allow the patient to experience presbyopic correction with the VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens and to determine the proper lens fit of the contact lenses (see Criteria of A Properly Fit Lens in the General Fitting Instructions). Since lens centration is important for multifocal toric lens performance, insert the trial lens with the steepest sagittal depth available.

C. VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens Selection

In is important when prescribing the VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens that you determine the stability, repeatability and drift angle of the lens axis so that you can prescribe the correct lens axis for your patient.

Initial Lens Power Selection

a) VISTAKON® (narafilcon B) Multifocal-Toric Contact Lenses come in the following ADD powers:

Lens "LOW" ="low" near ADD lens
Lens "MID" = "medium" near ADD lens
Lens "HIGH" = "high" near ADD lens

2. The cylinder power selected should be equal to the vertex adjusted cylinder power of the best corrected spectacle Rx.

Note: Any lens rotation is visually disturbing to the patient, so it's more practical to prescribe as weak a cylinder power as possible. A great deal of experience with patients has shown that it is possible to under-prescribe the minus cylinders near 180 ° ("with the rule") by as much as 30% and to under-prescribe minus cylinders near 90 ° ("against the rule") by as much as 20%. Therefore, if the cylinder correction is between two available cylinder powers, choose the less minus power.

Step 1	Determine: - Eye dominance (the methods described in MONOVISION SPHERE AND TORIC FITTING GUIDELINES may be used) - Spherical equivalent distance prescription (vertex corrected if necessary and rounded to less minus if between powers) - Near ADD
Step 2	Select the initial trial lens as follows: Initial Distance Power Selection For each eye, select the trial lens distance power that is closest to the patient's distance spherical equivalent. A patient with a spectacle Rx: (O.D.) = -3.00D –1.50D x 180, +1.50D ADD (O.S.) = -2.25D –1.50D x 170, +1.50D ADD Initial VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens distance power selection: (O.D.) = -3.00D –1.25D x 180 (O.S.) = -2.50D –1.25D x 170 Note: 1. Since the spectacle cylinder power is between two available VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens cylinder powers, choose the less minus contact lens cylinder power. Therefore, the initial VISTAKON® (narafilcon B) Multifocal-Toric Contact Lens cylinder power selection = +1.25D 2. Choose the diagnostic lens with an axis closest to the patient's spectacle cylinder axis. Select the near power of the lens based on the patient's ADD range as follows: ADD: +0.75 to +1.25 use a "LOW" near ADD lens on each eye ADD: +1.50 to +1.75 use a "MID" near ADD lens on each eye ADD: +2.00 to+2.50 use a "HIGH" near ADD lens on each eye
Step 3	Allow the lens to settle for a minimum 10 minutes.
Step 4	- Assess distance and near vision binocularly and monocularly. - Demonstrate the vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate and near. - Make adjustments in power as necessary (see **Multifocal-Toric Troubleshooting** below). The use of hand-held trial lenses is recommended.

Step 5	**A. Locate the Orientation Marks** To help determine the proper orientation of the toric lens, you'll find two primary marks about 1mm from the lens edge representing the vertical position on opposite ends of the lens at 6 and 12 o'clock (Fig. 1). Because of the lens' ballasting system, either mark can represent the vertical position – there is no "top" and "bottom" as in a prism-ballasted lens. You don't need to view both marks to assess orientation; simply look for the 6 o'clock mark as you would with a prism-ballasted lens. Figure 1 You'll need a biomicroscope and a 1mm or 2mm parallelepiped to highlight the marks when the lens is fitted to the eye. There are a number of techniques you can use to improve the visibility of the 6 o'clock mark. With your parallelepiped and medium magnification (10x or 15x), slowly pan down the lens, looking just below the direct illumination at the retroilluminated area. Backlighting the mark this way should make them more visible. Sometimes manipulating the lower lid may be necessary to uncover the mark. **B. Observe Lens Rotation and Stability** Observe the position and stability of the "bottom" mark. It usually stabilizes at the 6 o'clock position. If it does, calculation of the lens power will be straightforward. The 6 o'clock position is not a "must", however; the absolute requirement is that the axis position be stable and repeatable. The mark may stabilize somewhat left or right (drift) of the vertical meridian and still enable you to fit a toric lens for that eye, as long as the lens always returns to the same "drift axis" position after settling. The deviation can be compensated for in the final prescription. Your objective is to ensure that whatever position the initial lens assumes near 6 o'clock, this position must be stable and repeatable. With full eye movement or heavy blink, you may see the marks swing away, but they must return quickly to the original stable position. If the lens does not return quickly, you may need to select a different lens. **Assessing Rotation** Imagine the eye as a clock dial and every hour represents a 30° interval. If the orientation mark of the initial lens stabilizes somewhat left or right of the vertical position, the final lens will orient on the eye with the same deviation. You can use an axis reticule in the slit lamp or use a line-scribed lens in a spectacle trial frame to measure or estimate the "drift angle" of the cylinder axis. To compensate for this "drift", measure or estimate the "drift" and round it off into 5° increments, then add or subtract it from the refractive axis to determine the correct cylinder axis. Use the LARS (Left Add, Right Subtract) method to determine which direction to compensate. **C. Final Lens Determination** When the diagnostic lens has its axis aligned in the same meridian as the patient's refractive axis, a spherocylindrical over-refraction may be performed and visual acuity determined. However, in the case of crossed axes, such as when the diagnostic lens axis is different from the spectacle cylinder axis, it is not advisable

Step 5 (cont.)

In fitting contact lenses, it is customary to prescribe the full power in the sphere. In the cylinder, however, any lens rotation is visually disturbing to the patient, so it's more practical to prescribe as weak a cylinder as possible. So, here is how to determine the final lens power.

For the Sphere:

If sphere alone or combined sphere and cylinder Rx >±4.00D, compensate for vertex distance. If sphere alone or combined sphere and cylinder Rx ≤ ±4.00D, vertex compensation is not necessary.

For the Cylinder:

Adjust the axis by the drift angle using LARS. Choose a cylinder that is ≤ 0.50D from the refractive cylinder.

Case Examples

Example 1
Manifest (spectacle) refraction:
O.D. –2.50 -1.25 x 180 20/20
O.S. –2.00 -1.00 x 180 20/20

Choose a diagnostic lens for each eye with an axis as close to 180° as possible. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate, based on the patient's initial response to the lens.

Check the orientation of the axis mark. If the bottom axis mark is in the 6 o'clock position on both eyes, choose the appropriate cylinder as listed previously.

Here is the Rx Prescribed/Ordered:
O.D. -2.50 -1.25 x 180
O.S. –2.00 -0.75 x 180

Example 2
Manifest (spectacle) refraction:
O.D. –3.00 -1.00 x 90 20/20
O.S. –4.75 -2.00 x 90 20/20

Choose diagnostic lenses of –3.00 –0.75 x 90 for the right eye and –4.50 -1.75 x 90 for the left eye, the nearest lenses available to the spherical power and axis needed. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate. The orientation mark on the right lens rotates left from the 6 o'clock position by 10°.

The fitting indicates the following:

Right Eye

Compensate the 10° axis drift by adding it to the manifest refraction axis. Here is the Rx prescribed:
O.D. –3.00 –0.75 x 100

	Left Eye The lens on the left eye shows good centration, movement and a consistent tendency for the mark to drift right by 10° from the 6 o'clock position following a forced blink. Since the manifest refraction called for a power of –4.75D, adjust for the vertex distance and reduce the sphere by 0.25D and prescribe the –1.75D cylinder. Compensate for the 10° axis drift by subtracting it from the manifest refraction. Here is the Rx prescribed: O.S. –4.50 –1.75 x 80 C. If no adjustment was required and lens fit (see Criteria of A Properly Fit Lens in General Fitting Guidelines), axis orientation and rotational stability are acceptable, and the patient obtains acceptable visual performance, the trial lenses should be dispensed for up to one week of wear (see dispensing and follow up information in **PATIENT MANAGEMENT**). D. If the patient does not obtain acceptable visual performance, please see the **Multifocal-Toric Troubleshooting** section.

D. Multifocal-Toric Troubleshooting:

Ensure that the lenses have been inserted properly. Some patients will exhibit poor vision from a lens that is inside out, but still report good comfort and the lens will exhibit good fit characteristics. If a lens is inside out, remove the lens and insert it properly. Allow the patient to adapt to the lens again before evaluating vision.

If lenses were inserted properly, ensure that axis orientation and rotational stability is acceptable. If the axis is not located at the 6 o'clock position, adjust the axis as previously mentioned in Step 5. If the axis is oriented properly and the rotational stability is acceptable but the patient has unacceptable vision, conduct a distance over-refraction to ensure the patient has the least minus/most plus distance correction (i.e., ensure that the patient is not over-minused at distance). If the patient does not have the least minus/most plus distance correction, adjust the prescription and reassess the visual performance.

If the patient does have the least minus/most plus distance correction (i.e., is not over-minused at distance) but has unacceptable visual performance, please follow the suggestions below.

Unacceptable Near Vision:

Determine the amount of additional plus, or less minus, over one or both eyes that is acceptable while checking the effect on distance and near vision. If vision is still not acceptable change the non-dominant eye to the next highest ADD power.

Unacceptable Distance Vision:

Determine the amount of additional minus, or less plus, over one or both eyes that is acceptable while checking the effect on distance and near vision. If vision is still not acceptable change the dominant eye to the next lowest ADD power. If the patient is wearing two low ADD lenses change the dominant eye to a sphere lens with a power equal to the spherical equivalent distance prescription.

Unacceptable Distance and Near Vision:

Determine the amount of additional plus and/or minus over one or both eyes that is acceptable while checking the effect on distance and near vision. If additional plus and/or minus is not required change the lens power in the dominant eye to the next lowest ADD power and the lens power in the non-dominant eye to the next highest ADD power if applicable.

Prior to dispensing the lenses, check vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate and near. If distance and near vision are acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses, instructing the patient to return in one week for reassessment.

VI. MONOVISION (SPHERICAL AND TORIC FITTING GUIDELINES)

A. Patient Selection

Monovision Needs Assessment

For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than 1.00 D) in one eye may not be a good candidate for monovision correction with the VISTAKON® (narafilcon B) Contact Lens.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis), it should be determined by trial whether this patient can function adequately with monovision correction. Monovision contact lens wear may not be optimal for such activities as:

(a) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and

(b) driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with spectacles (multifocal, bifocal, trifocal, readers, progressives). Each patient should understand that Monovision, as well as other presbyopic alternatives, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments (e.g., reading a menu in a dim restaurant, driving at night in rainy/foggy conditions, etc.). During the fitting process, it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision and straight ahead and upward gaze that monovision contact lenses provide.

B. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following two methods for eye dominance can be used.

1. Ocular Preference Determination Methods

Method 1: Determine which eye is the "sighting eye". Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2: Determine which eye will accept the added power with the least reduction in vision. Place a hand-held trial lens equal to the spectacle near ADD in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near ADD lens over the right or left eye.

Other methods include the refractive error method and the visual demands method.

2. Refractive Error Method

For anisometropic correction, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

3. Visual Demands Method

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction, correct the eye on that side for near.

Example:
A secretary who places copy to the left side of the desk will function best with the near lens on the left eye.

C. Special Fitting Characteristics

1. Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may only require a distance lens.

Example:
A presbyopic emmetropic patient who requires a +1.75D ADD would have a +1.75D lens on the near eye and the other eye left without a lens.

A presbyopic patient requiring a +1.50D ADD who is –2.50D myopic in the right eye and –1.50D myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

2. Near ADD Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

3. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the General Fitting Instructions for base curve selection in this Package Insert.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine the distance correction and the near correction. Next determine the near ADD. With trial lenses of the proper power in place, observe the reaction to this mode of correction.

Allow the lenses to settle for about 20 minutes with the correct power lenses in place. Walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tests are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g., typewritten copy) at first and then graduate to newsprint and finally smaller type sizes.

After the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

4. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process, the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

Other Suggestions

The success of the monovision technique may be further improved by having your patient follow the suggestions below:

- Have a third contact lens (distance power) to use when critical distance viewing is needed.
- Have a third contact lens (near power) to use when critical near viewing is needed.

- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Monovision fitting can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of clear near vision and straight ahead and upward gaze with monovision.

The decision to fit a patient with a monovision correction is most appropriately left to the eye care professional in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the "VISTAKON® (narafilcon B) Patient Instruction Guide".

PATIENT MANAGEMENT

Dispensing Visit

- **PROVIDE THE PATIENT WITH A COPY OF THE APPROPRIATE VISTAKON® PATIENT INSTRUCTION GUIDE. REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING SCHEDULE.**
- Schedule a follow-up examination.

Follow-up Examinations

- Follow-up care (necessary to ensure continued successful contact lens wear) should include routine periodic progress examinations, management of specific problems, if any, and a review with the patient of the wear schedule and handling procedures.

- Recommended Follow-up Examination Schedule for VISTAKON® Contact Lenses (complications and specific problems should be managed on an individual patient basis):

1. One week from the initial lens dispensing to patient
2. One month post-dispensing
3. Every three to six months thereafter

Preferably, at the follow-up visits, lenses should be worn for at least six hours.

- Recommended Procedures for Follow-Up Visits:

1. Solicit and record patient's symptoms, if any.

2. Measure visual acuity monocularly and binocularly at distance and near with the contact lenses.

3. Perform an over-refraction at distance and near to check for residual refractive error.

4. With the biomicroscope, judge the lens fitting characteristics (as described in the General Fitting Guidelines) and evaluate the lens surface for deposits and damage.

5. Following lens removal, examine the cornea and conjunctiva with the biomicroscope and fluorescein (unless contraindicated).
    - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
    - The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear and/or a poorly fitting lens.
    - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

6. Periodically perform keratometry and spectacle refractions. The values should be recorded and compared to the baseline measurements.

If any observations are abnormal, use professional judgment to alleviate the problem and restore the eye to optimal conditions. If the criteria for successful fit are not satisfied during any follow-up examinations, repeat the patient's trial fitting procedure and refit the patient.

WEARING SCHEDULE

The wearing schedule should be determined by the Eye Care Professional. Patients tend to over wear the lenses initially. The Eye Care Professional should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the Eye Care Professional, are also extremely important.

DAILY DISPOSABLE WEAR (less than 24 hours, while awake)

- For daily disposable wear, VISTAKON® recommends that the VISTAKON® (narafilcon B) Contact Lenses be discarded upon removal.

The maximum suggested wearing time for these lenses is:

Day	Hours
1	6-8
2	8-10
3	10-12
4	12-14
5 and after	all waking hours

LENS CARE DIRECTIONS

When lenses are dispensed, the Eye Care Professional should provide the patient with appropriate and adequate warnings and instructions in accordance with the individual patient's lens type and wearing schedule.

For VISTAKON® (narafilcon B) Contact Lenses prescribed for daily wear single use only: The Eye Care Professional should review with patients that no cleaning or disinfection is needed. Patients should always dispose of lenses when they are removed and have replacement lenses or spectacles available.

CARE FOR A STICKING (NON-MOVING) LENS

If the lens sticks (stops moving), the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after a few minutes, the patient should immediately consult the Eye Care Professional.

EMERGENCIES
The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED
Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with methyl ether cellulose. The plastic package is marked with base curve, diopter power, diameter, color (visibility tint noted on visibility tinted product only), lot number and expiration date. [ADD power, cylinder and axis will be included as appropriate].

REPORTING OF ADVERSE REACTIONS
All serious adverse experiences and adverse reactions observed in patients wearing VISTAKON® Contact Lenses or experienced with the lenses should be reported to:

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, FL 32256
Tel: 1-800-843-2020
www.acuvue.com

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AT 11 09 00
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Revision Number: Version 1.0

Attachment 4

Contents The updated Patient Instruction Guide is provided in this Attachment.

PATIENT INSTRUCTION GUIDE
FOR SINGLE USE DAILY WEAR ONLY

VISTAKON® (narafilcon B) Contact Lenses (Spherical)
VISTAKON® (narafilcon B) Contact Lenses (Multifocal)
VISTAKON® (narafilcon B) Contact Lenses (Toric)
VISTAKON® (narafilcon B) Contact Lenses (Multifocal-Toric)

Visibility Tinted with UV Blocker

From the makers of ACUVUE® Brand Contact Lenses

TABLE OF CONTENTS

INTRODUCTION
INDICATIONS (USES) WEARING RESTRICTIONS
CONTRAINDICATIONS (REASONS NOT TO USE)
WARNINGS
PRECAUTIONS
ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)
PERSONAL CLEANLINESS FOR LENS HANDLING AND INSERTION
- Preparing the Lens for Wearing
- Opening the Multipack and Lens Package
- Handling the Lenses
- Placing the Lens on the Eye
- Centering the Lens
- Removing the Lens
- CARING FOR YOUR LENSES
- Basic Instructions
- Care for Sticking (Non-Moving) Lens
- Lens Case Cleaning and Maintenance
- Care for a Dried Out (Dehydrated) Lens
- Emergencies

INSTRUCTIONS FOR THE PRESBYOPIC PATIENT (MONOVISION & MULTIFOCAL)
WEARING AND APPOINTMENT SCHEDULES
PATIENT/EYE CARE PROFESSIONAL INFORMATION
GLOSSARY OF TECHNICAL TERMS
SYMBOLS KEY

CAUTION: Federal U.S.A law restricts this device to sale by or on the order of a licensed practitioner.

INTRODUCTION

The information and instructions contained in this booklet apply only to the VISTAKON® (narafilcon B) Contact Lenses. Your contact lenses are intended to be used for daily wear single use only within the VISTAKON® planned lens replacement system.

Please refer to the Glossary of Technical Terms for definitions of medical/technical terminology used in this booklet. In addition, the Symbols Key provides an explanation of symbols that may appear on the lens packaging. After the wearing period prescribed by your Eye Care Professional, your contact lenses should be discarded and replaced with a new sterile pair. If you have any questions, always ask your Eye Care Professional. By replacing your contact lenses on a daily basis, lens deposits, which can affect vision and cause irritation and discomfort to the eye, have little chance to build up over time as with conventional lens wear. When you discard the lens, you dispose of potential deposit build-up problems. Your contact lenses are visibility tinted with a UV Blocker. An ultraviolet (UV) radiation absorbing ingredient is used to block UV radiation.

For your eye health, it is important that your contact lenses be worn only as prescribed by your Eye Care Professional. Your Eye Care Professional should be kept fully aware of your medical history. Your Eye Care Professional will tailor a total program of care based on your specific needs. He or she will review with you all instructions for lens handling and care, including how to safely and easily open the packaging. You will also be instructed on how to properly insert and remove lenses. This booklet will reinforce those instructions.

If you have any questions, always ask your Eye Care Professional.

INDICATIONS (USES) AND WEARING RESTRICTIONS

All VISTAKON® (narafilcon B) Soft Contact Lenses with UV Blocker help protect against transmission of harmful UV radiation to the cornea and into the eye.

The VISTAKON® (narafilcon B) Soft Contact Lens (spherical) is indicated 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® (narafilcon B) Multifocal Soft Contact Lens is indicated 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® (narafilcon B) Toric Soft Contact Lens is indicated 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® (narafilcon B) Multifocal-Toric Soft Contact Lens is indicated 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.

Your Eye Care Professional should prescribe the lenses for daily wear single use only. The Eye Care Professional will determine your wearing schedule. Your lenses are to be discarded upon removal. Therefore, no cleaning or disinfecting is required.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the VISTAKON (narafilcon B) Contact Lens when any of the following conditions exist:
- Inflammation or infection in or around the eye or eyelids
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
- Any previously diagnosed condition that makes contact lens wear uncomfortable.
- Severe dry eye
- Reduced corneal sensitivity (corneal hypoesthesia)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or surrounding tissues (adnexa) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated

WARNINGS

What you should know about Contact Lens Wear

- Problems with contact lenses or lens care products could result in serious injury to the eye. Proper use and care of your contact lenses and lens care products, including lens cases, are essential for the safe use of these products.
- Eye problems, including a sore or lesion on the cornea (corneal ulcers) can develop rapidly and lead to loss of vision.
- The risk of an infected sore or lesion on the cornea (ulcerative keratitis) greater for people who wear extended wear contact lenses than for those who wear daily wear lenses.
- When daily wear users wear their lenses overnight (outside the approved use), the risk of infected sore or lesion on the cornea (ulcerative keratitis) is greater than among those who do not wear them while sleeping.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.
- The risk of ulcerative keratitis among contact lens users who smoke is greater than among non-smokers.
- If you experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, you should immediately remove your lenses and promptly contact your Eye Care Professional. It is recommended that you see your Eye Care Professional routinely as directed.

***WARNING**: **UV absorbing contact lenses are not substitutes for protective UV absorbing eyewear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.**

Note: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your Eye Care Professional for more information.

PRECAUTIONS

Handling Precautions:

• **DO NOT** use if the sterile blister package is opened or damaged.
• Before leaving the Eye Care Professional's office, you should be able to promptly remove the lenses or should have someone else available who can remove the lenses for you.
• **Always wash and rinse your hands before handling lenses**. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in your eyes or on your lenses. It is best to put on your lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
• **DO NOT** touch your contact lenses with your fingers or hands if they are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to your eye.
• **Carefully** follow the handling, insertion, removal and wearing instructions in this booklet and those prescribed by the Eye Care Professional.
• **Always** handle lenses carefully and avoid dropping them.
• **Never** use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour the lens and the packing solution into the hand.
• **Do not** touch the lens with your fingernails.

Lens Wearing Precautions:

• You should remove your lenses immediately if your eyes become red or irritated.
• **Never** wear your lenses beyond the period recommended by your Eye Care Professional.
• If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and **keep your eyes closed** until the spray has settled.
• **Avoid** all harmful or irritating vapors and fumes while wearing lenses.
• **Ask** your Eye Care Professional about wearing contact lenses during sporting activities, especially swimming and other water sports. Exposing contact lenses to water during swimming or while in a hot tub **may increase the risk of eye infection** from microorganisms.
• **Always throw away** lenses worn as prescribed by your Eye Care Professional.

Lens Care Precautions:

• The Eye Care Professionals should review with patients that no cleaning or disinfecting is needed with daily single use lenses. Patients should always dispose of lenses when they are removed and have replacement lenses or spectacles available.

Other Topics to discuss with Your Eye Care Professional:

• If you wear your contact lenses to correct presbyopia using monovision or if your contact lenses are Multifocal or Multifocal-Toric to correct presbyopia you **may not** achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered by our eye care professional in conjunction with you when selecting the most appropriate type of lens for you.

• **Always** contact your Eye Care Professional before using any medicine in your eyes.
• **Be aware** that certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers and those for motion sickness may cause dryness of the eye, increased lens awareness or blurred vision. Always inform your eye care professional if you experience any problems with your lenses while taking such medications. Depending on the severity, your eye care professional may prescribe the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.
• **Be aware** that if you use oral contraceptives, you could develop visual changes or changes in lens tolerance when using contact lenses.
• As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes.

Who should know that you are wearing Contact Lenses:

• **Inform** your doctor (Health Care Professional) about being a contact lens wearer.
• **Always** inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.

ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)

Be aware that the following problems may occur when wearing contact lenses:

• Your eyes may burn, sting and/or itch.
• There may be less comfort than when the lens was first placed on your eye.
• There may be a feeling of something in your eye (foreign body, scratched area).
• There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers and corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.
• There may be excessive watering, unusual eye secretions or redness of your eye.
• Poor visual acuity, blurred vision, rainbows or halos around objects, sensitivity to light (photophobia) or dry eyes may also occur if your lenses are worn continuously or for too long a time.

You should conduct a simple 3-part self-examination at least once a day.

Ask yourself:
- How do the lenses feel on my eyes?
- How do my eyes look?
- Do I continue to see well?

If you report any problems, you should IMMEDIATELY REMOVE YOUR LENS.

If the discomfort or problem stops, you should look closely at the lens.

If the lens is in any way damaged, you SHOULD NOT put the lens back on your eye. You should discard the lens and insert a new fresh lens on your eye.

If your lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, you should dispose of the lens and insert a new fresh lens.

If the problem continues, you SHOULD NOT put the lens back on your eye but IMMEDIATELY CONSULT YOUR EYE CARE PROFESSIONAL.

When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. **Seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

PERSONAL CLEANLINESS FOR LENS HANDLING AND INSERTION

1. Prepare the Lens for Wearing

It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:

- Always wash your hands thoroughly with a mild soap, rinse completely and dry with a lint free towel before touching your lenses.
- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips, and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.

Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

2. Opening the Multipack and Lens Package

Multipack

Each multipack contains individually packaged lenses. Each lens comes in its own lens package designed specifically to maintain sterility. You may choose to keep your lenses inside the multipack for storage until you are ready to use them.

Lens Package

To open an individual lens package, follow these simple steps:

1. Shake the lens package and check to see that the lens is floating in the solution.

2. Peel back the foil closure to reveal the lens. By stabilizing the lens package on the table-top, you will minimize the possibility of a sudden splash.

Occasionally, a lens may adhere to the inside surface of the foil when opened, or to the plastic package itself. This will not affect the sterility of the lens. It is still perfectly safe to use. Carefully remove and inspect the lens following the handling instructions.

3. Handling the Lenses

• When you first get your lenses, be sure that you are able to put the lenses on and remove them before leaving your Eye Care Professional's office.
• Develop the habit of always working with the same lens first to avoid mix-ups.
• Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or tears. If the lens appears damaged, do not use it. Use the next lens in the multipack.

4. Placing the Lens on the Eye

Remember, always start with the same eye.

Once you have opened the lens package, removed, and examined the lens, follow these steps to apply the lens to your eye:

1. BE SURE THE LENS IS NOT INSIDE-OUT by following either of the following procedures:
   • Place the lens on the tip of your index finger and check its profile. The lens should assume a natural, curved, bowl-like shape. If the lens edges tend to point outward, the lens is inside out. Another method is to gently squeeze the lens between the thumb and forefinger. The edges should turn inward. If the lens is inside out, the edges will turn slightly outward.

OR

   • Place the lens on the tip of your index finger and, looking up at the lens, locate the numbers 123. 1-2-3 indicates correct orientation while a reverse of 1-2-3 indicates the lens is inside out. If the lens is inside out (reverse 1-2-3), invert the lens and locate the numbers again to confirm correct lens orientation.

2. Place the middle finger of the same hand close to your lower eyelashes and pull down the lower lid.

3. Use the index finger or middle finger of the other hand to lift the upper lid.

4. Place the lens on the eye.

5. Gently release the lids and blink. The lens will center automatically

6. Use the same technique when inserting the lens for your left eye

There are other methods of lens placement. If the above method is difficult for you, your Eye Care Professional will provide you with an alternate method.

After you have successfully inserted your lenses, you should ask yourself:
- Do I see well?
- How do the lenses feel on my eyes?
- How do my eyes look?

Note: If after placement of the lens, your vision is blurred, check for the following:

- The lens is not centered on the eye (see "Centering the Lens", next in this booklet).
- If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:

    a. Cosmetics or oils on the lens. Dispose of the lens and insert a new fresh lens.
    b. The lens is on the wrong eye.
    c. The lens is inside out (it would also not be as comfortable as normal).

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your Eye Care Professional.

If a lens becomes less comfortable than when it was first inserted or if it is markedly uncomfortable upon insertion, remove the lens immediately and contact your Eye Care Professional.

If your examination shows any problems, IMMEDIATELY REMOVE YOUR LENSES AND CONTACT YOUR EYE CARE PROFESSIONAL.

5. Centering the Lens

A lens, which is on the cornea, will very rarely be displaced onto the white part of the eye during wear. This, however, can occur if insertion and removal procedures are not performed properly. To center a lens, follow either of these procedures:

a. Close your eyelids and gently massage the lens into place through the closed lids.

OR

b. Gently manipulate the off-centered lens onto the cornea while the eye is opened using finger pressure on the edge of the upper lid or lower lid.

6. Removing the Lens

Always remove the same lens first.

a. Wash, rinse and dry your hands thoroughly.

CAUTION: Always be sure the lens is on the cornea before attempting to remove it. Determine this by covering the other eye. If vision is blurred, the lens is either on the white part of the eye or it is not on the eye at all. To locate the lens, inspect the upper area of the eye by looking down into a mirror while pulling the upper lid up. Then inspect the lower area by pulling the lower lid down.

b. There are two recommended methods of lens removal: the Pinch Method and the Forefinger and Thumb Method. You should follow the method that is recommended by your Eye Care Professional.

Pinch Method:

1. Look up, slide the lens to the lower part of the eye using the forefinger.

2. Gently pinch the lens between the thumb and forefinger.

3. Remove the lens.

Forefinger and Thumb Method:

1. Place your hand or towel under your eye to catch the lens.

2. Place your forefinger on the center of the upper lid and your thumb on the center of the lower lid.

3. Press in and force a blink. The lens should fall onto your hand or the towel.

Once the lens is removed, simply follow the lens care directions recommended by your Eye Care Professional.

> **Note:** The lens may come out, but remain on the eyelid, finger or thumb.

4. Remove the other lens by following the same procedure.

5. Follow the required lens care procedures described under the heading, "Caring For Your Lenses (Cleaning, Rinsing, Disinfecting, Storage and Rewetting/Lubricating)".

> **Note**: If these methods of removing your lens are difficult for you, your Eye Care Professional will provide you with an alternate method.

CARING FOR YOUR LENSES

1. Basic Lens Care Instructions

If you require only vision correction, but will not or cannot always use the recommended care routine for your lenses, or are unable to put on and remove lenses or have someone available to place and remove them, you should not try to get and wear contact lenses.

- When you first get your lenses, be sure to put the lenses on and remove them while you are in your Eye Care Professional's office.
- Always wash, rinse, and dry your hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.
- Never rinse your lenses in water from the tap. There are two reasons for this:
    a. Tap water may contain impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
    b. You might lose your lens down the drain.

For Single Use Daily Wear:

Remember, there is no cleaning or disinfection needed with VISTAKON® (narafilcon B) Contact Lenses prescribed for daily single use wear only. Always dispose of lenses when they are removed and have replacement lenses or spectacles available.

2. Care For A Sticking (Non-moving) Lens

If a lens sticks (stops moving) on your eye, apply a few drops of the recommended lubricating solution. You should wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues, you should immediately consult your Eye Care Professional.

3. Lens Case Cleaning and Maintenance

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer and allowed to air dry. Lens cases should be replaced at regular intervals, as recommended by the lens case manufacturer or your Eye Care Professional.

4. Care For A Dried Out (Dehydrated) Lens

If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle. If this happens, dispose of the lens and use a new fresh one.

5. Emergencies

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

INSTRUCTIONS FOR THE PRESBYOPIC PATIENT (MONOVISION & MULTIFOCAL)

• You should be aware that, as with any type of lens correction, there are advantages and compromises to presbyopic contact lens correction. The benefit of clear near vision in straight ahead and upward gaze that is available with your contact lenses for monovision and multifocal correction may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to this. Symptoms, such as mild blurred vision and variable vision, may last for a brief period or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your chances for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations that are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first days of wearing your lens. It is recommended that you only drive with Monovision correction if you pass your state drivers license requirements with Monovision correction.

• Some presbyopic patients require supplemental spectacles to wear over your contact lenses for monovision or multifocal correction to provide the clearest vision for critical tasks. You should discuss this with your Eye Care Professional.

• Some presbyopic patients will never be fully comfortable functioning under low levels of lighting, such as driving at night. If this happens, you may want to discuss with your Eye Care Professional having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.

For monovision patients, if you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required. It is important that you follow your Eye Care Professional's suggestions for adaptation to presbyopic contact lens correction. You should discuss any concerns that you may have during and after the adaptation period

.

• The decision to be fit with Monovision or multifocal correction is most appropriately left to the Eye Care Professional, in conjunction with you, after carefully considering and discussing your needs.

WEARING AND APPOINTMENT SCHEDULE

Prescribed Wearing Schedule

Day	Wearing Time (Hours)
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	

Appointment Schedule
Your appointments are on:
Minimum number of hours lenses to be worn at time of appointment:
Month: Year:
Time: Day:

PATIENT/EYE CARE PROFESSIONAL INFORMATION

Next Appointment:
Date:
Dr:
Address:
Phone:

Day Date Hours Worn	Day Date Hours Worn
1	1
2	2
3	3
4	4
5	5
6	6
7	7

IMPORTANT: In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYE CARE PROFESSIONAL IMMEDIATELY.

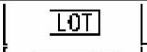
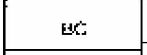
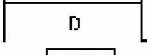
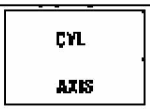
NOTES

Glossary of Technical Terms

Term	Definition
Adnexa	Tissues surrounding the eyeball
Ametropia	Abnormal vision requiring correction for proper focus
Anterior chamber	Internal portion of the eye, between the cornea and iris
Aphakic	An eye that does not have its natural lens (example: after cataract surgery)
Aspherical contact lens	A lens with a curve that is not round, but has different shapes across its surface
Astigmatism	A condition where the cornea is not equally curved in all parts of its surface. It is somewhat oval in shape, causing the visual image to be out of focus (blurred).
Conjunctiva	Membrane that lines the eyelids and the white part of the eye
Conjunctivitis	Inflammation of the conjunctiva
Cornea	Clear front part of the eye that covers the iris, pupil and anterior chamber
Corneal erosion	Wearing away of the surface of the cornea
Corneal staining	When a dye is put onto the eye and shows problems with the corneal surface
Corneal ulcer	A sore or lesion on the cornea
Disinfection	A process that kills harmful microorganisms (germs) which can cause serious eye infections
Edema	Swelling of tissue from excess fluid accumulation
Hydrophilic material	"Water loving" or water absorbing substance
Hyperopia	Farsightedness
Infiltrate	Redness
Iritis	Inflammation of the colored part of the eye (iris)
Inflammation	Swelling, redness, and pain
Monovision	A correction method for presbyopia (loss of reading vision) using contact lenses; one eye is fitted for distance, the other for near vision
Multifocal contact lens	A lens that can correct for both distance and near vision
Myopia	Nearsightedness
Neovascularization	Blood vessels growing into the cornea
Phakic	An eye that possesses its natural lens
Presbyopia	Condition in which as the lenses in the eyes lose some of their elasticity, as occurs with aging, they lose some of their ability to change focus for different distances. Usually becomes significant after age 45.
Spherical contact lens	A lens with a continuously rounded curve
Tarsal abnormalities	Problems with the eyelids
Toric contact lens	A lens with two different optical powers at right angles to each other for the correction of astigmatism`
Toric-Multifocal contact lens	A lens that can correct for both distance and near vision with two different optical powers at right angles to each other for the correction of astigmatism
Ulcerative keratitis	An infected corneal ulcer
UV (Ultraviolet)	Light from the sun that can be harmful to the eye

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	See Instruction Leaflet
	Use By Date (expiration date)
	Batch Code
	Sterile Using Steam or Dry Heat
	Diameter
	Base Curve
	Diopter (lens power)
	UV Blocking
	Fee Paid for Waste Management
	Peel Back Foil
	Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner
	Center Thickness
	Visibility Tinted Lens Orientation Correct
	Visibility Tinted Lens Inside Out
	Cylinder Power
	Axis
LOW	"Low" near ADD
MID	"Medium" near ADD
HIGH	"High" near ADD

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Date 09/09

Attachment 5

Contents The updated Manufacturing Flow Chart is provided in this Attachment.

Manufacturing Process for VISTAKON® (narafilcon B) Contact Lenses

(b)(4)