

Biocompatibles Eyecare Inc.
 Parametric Release 510(k)
 methafilcon A hydrophilic contact lenses

MAR 23 1998

SAFETY AND EFFECTIVENESS SUMMARY

1. **Name and address of submitter** Biocompatibles Eyecare Inc.
 1215 Boissevain Avenue
 Norfolk VA USA 23507
 Contact Person: Lisa Hahn

 Telephone number: 800-225-3069 or 757-664-2421

 Date summary prepared: January 15, 1998
2. **Identification of Device** Trade Name: LL-55 (methafilcon A) Soft Contact Lens

 Common or Usual Name: Soft (hydrophilic) Contact Lens (daily wear)
 Classification: Group II
3. **Predicate Device** LL-55 (methafilcon A) Contact Lens
4. **Description of Device**

The LL-55 contact lenses are available as lathe cut spherical lens. The lens material (methafilcon A) is a hydrophilic polymer of hydroxyethylmethacrylate and methacrylic acid.

5. Intended Use (indications)

LL-55 (methafilcon A) Soft Hydrophilic Contact Lenses are indicated for daily wear for the correction of visual acuity in not aphakic persons with non-diseased eyes that are myopic or hyperopic and exhibit astigmatism of 2.00D or less that does not interfere with visual acuity.

6a Characteristics comparison of predicate to this device

Design, material, and chemical composition remain unchanged from those approved in Premarket 510(k) Notification K941877

6b Clinical tests and results

Not performed; lenses remain unchanged from approved Premarket 510(k) Notification K941877.

6c Non Clinical tests and results

The final product lenses will be processed through packaging, sealing, labeling, sterilization and staged for QC release in same manner as currently established and validated. The only change to the process will be the elimination of Biological Indicators. This submission supports use of physical parameters of sterilization cycle to meet specifications as the basis for sterility release mechanism.

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6c 1. Validation of the Steam Sterilization Process:

Validation of the steam sterilization process demonstrated that the steam sterilizer is capable of achieving more than a 10^{-6} sterility assurance level (SAL) upon completion of a calculated exposure time of twenty (20) minutes and an exposure temperature of 121° C on normal finished product lenses.

6c 2. Product Bioburden Monitoring

Results obtained monthly over a 5 month period have determined that bioburden of product in production is well controlled. Presterilization bioburden results are consistently significantly below both 1000 vegetative CFU and 40 spore forming CFU. Each month average CFU per presterilized product unit for the 5 months from July 1997 to November 1997 is low; counts range from a high of 294 to a low of 29 vegetative CFU and less than 1 sporeforming CFU.

The process used to determine bioburden has been validated. Validation included assessment of the adequacy of the technique used to remove micro-organisms from the final lens product, assessment of the adequacy of the technique used to enumerate removed micro-organisms, including micro-biological counting techniques and culture conditions; and establishment of the recovery efficiency for the method used in order that the correction factor be calculated.

6c 3. Laminar Flow Workstation Bioburden Level

Settle plates are routinely used in the manufacturing facility laminar flow workstations to monitor the airborne bioburden. Results are consistently low.

Surface touch plates are used to routinely sample bioburden levels on workstation surfaces. Results are consistently low.

6c 4. Calibration/ Certification of Relevant Equipment

The steam sterilizer was calibrated to demonstrate that the apparatus is operating within manufacturer design specifications. The sterilizer successfully demonstrated its capability to regulate temperature. The pressure gauge on the sterilizer also successfully demonstrated it's ability to display and record pressure.

Upon performing the zero and span calibration procedures on the data logger all output temperatures from the 10 validation thermocouple readings deviated less than 1°C from the setpoint.

The pressure readings were monitored and pressure was held to 15 psi \pm 0.5 psi during the timing portion of the cycle.

Annual calibration of steam sterilizer is performed to verify consistent parameter measurement recordings. Additionally annual sterilizer validations are performed to

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ensure consistent operations of sterilizer to specifications and to verify adequacy of cycle times. Recent validation results demonstrated that the sterilizer is in compliance with operating specifications and cycle time exceeds time necessary to achieve 10^{-6} sterility assurance level (SAL).

To ensure consistent operating efficiency, annual certification of the laminar air flow workstations is performed. Recent certification results demonstrated that the laminar air flow workstations were in compliance with Federal Standard 209E to Class 100 requirements.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 1998

Ms. Lisa Hahn
Director of Regulatory Affairs
Biocompatibles Eyecare, Inc.
1215 Boissevain Avenue
Norfolk, VA 23507

Re: K980218
Trade Name: LL-55 (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear
(Parametric release)
Regulatory Class: II
Product Code: 86 LPL
Dated: January 15, 1998
Received: January 16, 1998

Dear Ms. Hahn:

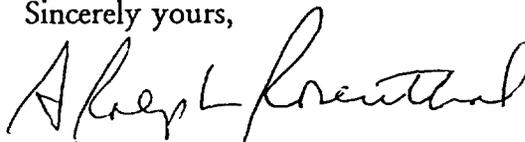
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number : K980218

Device Name: LL-55 (methafilcon A) Daily Wear Contact Lens

Indication for use:

LL-55 (methafilcon A) Soft Hydrophilic Contact Lenses are indicated for daily wear for the correction of visual acuity in not aphakic persons with non-diseased eyes that are myopic or hyperopic and exhibit astigmatism of 2.00D or less that does not interfere with visual acuity.

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

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Myra Smith
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K980218

Prescription Use X OR Over the counter use _____

(Optional format 1-2-96)