

April 30, 1997

JUL 14 1997



510(K) SUMMARY

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134-2099
(817) 293-0450

Submitted by:

Michael E. Pfleger
Associate Director, Regulatory Affairs
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, Texas 76132
(817) 551-4877 (Phone)
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Device Name:

Common Name: Contact Lens Case
Proprietary Name: Alcon Contact Lens Case

Device Classification:

Contact lens have not been officially classified, but have been recommended by the Ophthalmic Devices Panel to be classified in Class II and have historically been regulated through the 510(k) process.

Description:

The Alcon Contact Lens Case is intended for use for storage of soft (hydrophilic), rigid gas permeable, and hard contact lenses during chemical disinfection. It consists of a side by side double well plastic case with two screw-on plastic closures. A drawing of the Alcon Contact Lens Case is provided.

Performance:

The Alcon Contact Lens Case is designed to have an overflow capacity of 5.0 mL in each lens well. This will be a sufficient volume to assure that the contact lens will remain immersed under use conditions.

Substantial Equivalence Comparison:

The Alcon Contact Lens Case is identical in its intended use to the OPTI-FREE[®] Lens Case (K931620) and the OPTI-LENS[®] Lens Case (K915082). It is intended for storage of soft (hydrophilic), rigid gas permeable, and hard contact lenses during chemical disinfection. All the materials currently being used in the lens cases or proposed in this submission have passed the relevant physico-chemical, and toxicological tests.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Michael E. Pflieger
Associate Director, Regulatory Affairs
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099

JUL 14 1997

Re: K971618
Trade Name: Alcon Contact Lens Case
Regulatory Class: unclassified
Product Code: LRX (0)
Dated: April 30, 1997
Received: May 2, 1997

Dear Mr. Pflieger:

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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

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 (if known): unknown

Device Name: The Alcon Contact Lens Case

Indications for Use:

For storage of soft (hydrophilic), rigid gas permeable, and hard contact lenses during chemical disinfection.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. C. Brown, Ph.D. 

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K971618

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X