2/11/99

K990044

Exhibit 4

510(k) Summary
December 30, 1998

Submitted by:

Daniel J. Manelli
Farkas & Manelli, P.L.L.C.
2000 M Street NW (#700)
Washington, DC 20036
202-261-1000

On behalf of Lobob Laboratories, inc.
140 Atteberry Lane
San Jose, CA 95131-1410

Device Classification:	Class II -Soft (hydrophilic) contact lens care product (21 CFR 886.5928)
Trade Name:	Lobob Universal Contact Lens Cleaner
Predicate Device:	Lobob Cleaner (P950031)

Safety and Effectiveness Information:

The device is currently marketed as a cleaner for rigid gas permeable (RGP) and hard (PMMA) contact lenses. The current notification is for the added indication of cleaning soft (hydrophilic) contact lenses.

Lobob performed non-clinical and clinical testing on the device. The non-clinical testing supports the safety and effectiveness of the device from microbiology, toxicology, chemistry and manufacturing perspectives. Clinical data were obtained from a multi-center study involving a hydrophilic contact lens consisting of 72 eyes followed for 3 months. This data was submitted to and evaluated by FDA in connection with its approval of PMA No. P950031.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 1999

Lobob Laboratories, Inc.
c/o Mr. Daniel J. Manelli
FARKAS & MANELLI, P.L.L.C.
2000 M Street (#700)
Washington, DC 20036

Re: K990044
Trade Name: Lobob Universal Contact Lens Cleaner
Regulatory Class: II
Product Code: 86 LPN
Dated: January 21, 1999
Received: January 22, 1999

Dear Mr. Manelli:

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

revised 01/21/99

Exhibit 3

510(k) Number (if known): K990044

Device Name: Lobob Universal Contact Lens Cleaner

Indications For Use:

To clean soft (hydrophilic), rigid gas permeable (silicone acrylate, fluoro-silicone acrylate) and hard (PMMA) contact lenses.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K990044

Prescription Use____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)