4/9/99

CONFIDENTIAL

K990224

8. 510(k) Summary of Safety and Effectiveness

In accordance with CFR 807.92 (April 26, 1992), the following information is submitted:

1. Name: Labtician Ophthalmics, Inc.
   Address: 2140 Winston Park Dr. Unit #6
   Oakville, ON L6H 5V5 Canada

   Telephone: 905 829-0055
   Fax 905 829-0056

   Contact: R. David Sculati

   Date of Summary Preparation: January 22, 1999

2. Name of Device: Labtician Lid Load™ External Eyelid Sizing Weights
   Common Name: External Eyelid Sizing Weights
   Classification Name: None known

3. Predicate Device: EyeClose External Eyelid Weights, K940974.

4. Device Description:

   Labtician Lid Load External Eyelid Sizing Weights are spherically radiused strips of pure tantalum (99.5%), constructed in twelve sizes ranging from 0.6 grams to 2.8 grams in 0.2 gram increments.

   A Labtician Lid Load External Eyelid Sizing Weight is attached to the outer skin of the upper eyelid with a double coated adhesive tape strip or other suitable adhesive.

   The physical specifications and materials used in the construction of Labtician lid Load External Eyelid Sizing Weights are identical to the EyeClose External Eyelid Weights, with the exception that Labtician Lid Load External Eyelid Sizing Weights are unpainted.

5. Intended Use:

   Sizing weights are used to determine the correct gold eyelid weight to be implanted in the treatment of lagophthalmos. The sizing weights are used by the physician who affixes a succession of external eyelid weights to the outer surface of the eyelid until the proper eyelid closure is attained. The corresponding implantable gold eyelid weight is then prescribed for implantation.

   Today, the most commonly used and successful surgical treatment of lagophthalmos is implantation of the gold eyelid load weight. This device is used to allow the upper lid to close by force of gravity when the levator palpebrae muscle is relaxed.

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6. Technological Characteristics of the Device:
Labtician Lid Load External Eyelid Sizing Weights are produced to the same specifications as the EyeClose External Weights with the exception that the Labtician Lid Load External Sizing Weights are unpainted.

Labtician Lid Load External Eyelid Sizing Weights are constructed of pure tantalum (99.5%). The weights are designed in a rectangular shape with a spherical radius of curvature of 12.7 mm which conforms to the shape of the eye. All edges are smoothly rounded.

SUBSTANTIAL EQUIVALENCE COMPARISON

	Labtician Lid Load Extenal Eyelid Sizing Weight	Med Dev EyeClose External Eyelid Weight
Indications for Use	Same*	Same**
Target Population	Same	Same
Design	Same	Same
Materials	Same***	Same****
Performance	Same	Same
Sterility (non sterile)	Same	Same
Biocompatibility	Same	Same
Mechanical Safety	Same	Same
Anatomical Site	Same	Same
Human Factors	Same	Same

* affixed externally-used for determining the correct size gold weight to be implanted in treatment of lagophthalmos.
** affixed externally-used for treatment of lagophthalmos
***pure tantalum-unpainted ****pure tantalum-painted on outer surface

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 1999

R. David Sculati
Vice President & General Manager
Labtician Ophthalmics, Inc.
2140 Winston Park Drive, Unit 6
Oakville, Ontario,
Canada, L6H 5V5

Re: K990224
Trade Name: Labtician Lid Load™ External Eyelid Sizing Weight Set
Regulatory Class: Unclassified
Product Code: 86 MML
Dated: January 22, 1999
Received: January 25, 1999

Dear Mr. Sculati:

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): K990224

Device Name: Labtician Lid Load External Sizing Weights

Indications For Use:

Statement of Indications for Use

Labtician Lid Load External Eyelid Sizing Weights are used by the physician to determine the correct gold eyelid weight to be implanted in the treatment of lagophthalmos.

Labtician Lid Load External Eyelid Sizing Weights are used by the physician who affixes a succession of external eyelid weights to the outer surface of the eyelid using until the proper eyelid closure is attained. Because the levator muscle seems to strengthen after the weight is added, the optimal weight for implantation is ususally that which holds lid about 1.0 mm lower than the normal lid as the patient looks straight ahead.
The corresponding implantable gold eyelid weight is then prescribed for implantation.

Sizing weights are not designed to be implanted, and are provided non-sterile and are re-usable following cleaning with soap and water and/or alcohol and rinsing with tap water.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Monzé

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K990224