AUG 25 1998

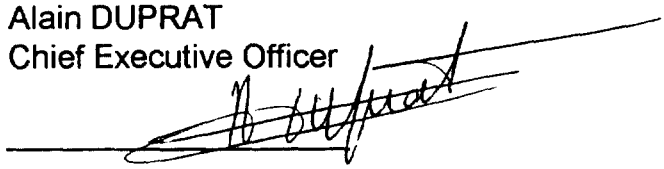
K981742

SUMMARY OF SAFETY AND EFFECTIVENESS

1. Sumitter's identification :

a. MORIA
15 rue Georges Besse
92160 ANTONY
FRANCE

b. Contact person : Alain DUPRAT
Chief Executive Officer



c. Date Summary Prepared : May, 18th, 1998

2. Device name :

Trade Name : ONE UP keratome head

3. Classification name :

Microkeratome

4. Subtantial equivalence :

Substantial equivalence is being claimed to the following legally marketed devices

1) Automated disposable keratome
Company : LASERSIGHT Technologies, Inc.
510 K : K 974 004

2) PLANCON microlamellar keratome (single piece head)
Company : PLANCON INSTRUMENTS
510 K : K 970 377

5. Device description

a. General device description

The ONE UP disposable keratome head and suction ring are identical in design, concept and principle to the predicate PLANCON microlamellar keratome single piece head K 970 377, the only difference being that the keratome head, the ring and the handle are made of high density plastic material.
The stainless steel blade and the plastic blade holder are similar to the blade and blade holder of the above predicate.
The keratome head has dovetails guides which engage in the dovetails of the suction ring.
The blade oscillates by means of the same turbine of the predicate device referred above.
The power unit is similar in characteristics, principles and functions to the power units of legally marketed keratomes.
The ONE UP disposable keratome head comes preassembled and presterilized in a copolyester sealed tray, sealed with TYVEK ® peel off cover.
The sterilisation is performed under validated gamma radiation cycle with sterility assurance level of 10^{-6} and dosimetric release.
The plastic materials used for patient contact portion of device have been tested according to classification of USP and the grades used passes classes I through VI, and are deemed to be biocompatible.

b. System composition

- Power unit
- Keratome head
- Keratome blade
- Nitrogen powered turbine
- Footswitches
- Applanator lenses
- Suction rings

b1) Power unit

The power unit includes pumps for producing vacuum.
The power unit has been designed to operate the keratome by means of 12 V DC motor or by means of nitrogen motor.
Only one of the above power options can be selected at the time by means of a 2 position switch in the front panel.

The front panel has several displays and features :

- Vacuum pressure gauge,
- Gas pressure gauge,
- Battery level indicator,
- Battery charge indicator,
- Connectors :
  - Gas inlet,
  - Gas outlet,
  - Vacuum outlet,
  - Foot pedals,
  - Battery charger.

All connectors are of different type for preventing connecting mistakes.

b2) Turbine

The turbine motor is gas powered.
The recommended gas is nitrogen but the turbine will accept any medical gas.
The turbine is not specific to this device. It is already used in the U.S. in particular for dental use. It has been in the market for seven years.

b3) Keratome head

The keratome head adapts to the turbine by means of a threaded part.

The keratome head includes the blade which is moved by the turbine.

Different heads are available in order to adjust the thickness of the cut.

The head is a single piece, thus no assembly or adjustment are necessary. This is a major improvement which avoids the risk of uncorrect assembly and results in a much safer procedure.

b4) Suction rings

The suction rings are used to fixate and pressurize the eye and provide a base for the microkeratome. High precision dovetails ensure accurate cut depth and translation accross the cornea.

6. Statement of intended use

The ONE UP keratome head is intended for use in patient undergoing surgery or other treatment requiring initial lamellar resection of the cornea, circular and of predetermined diameter and thickness.

7. Discussion of tests and results

Keratomes have been used for lamellar keratoplasty for more than 30 years. The ONE UP disposable keratome head performs equivalently to the predicate devices for creating circular lamellar resection of a predetermined diameter and thickness, and do not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 1998

MORIA S.A.
ATTN: Alain Duprat
General Manager
15 Rue Georges Besse
Antony, France

Re: K981742
Trade Name: One up Disposable Keratome Head
Regulatory Class: I
Product Code: 86 HNO
Dated: July 10, 1998
Received: July 13, 1998

Dear Mr. Duprat:

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 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). 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) :

Device Name :

ONE UP disposable keratome head

Indications for use :

The ONE UP disposable keratome head is intended for use in patient undergoing surgery or other treatment requiring initial lamellar resection of the cornea, circular and of predetermined diameter and thickness.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daryl L. Kaufman

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K981742

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use ___ (Optional Format 1-2-96)