

JUL 24 1998

K981741

MORIA  
CARRIAZO BARRAQUER microkeratome

May 15, 1998  
Premarket Notification  
Section 5 page 1

**SUMMARY OF SAFETY AND EFFECTIVENESS**

**1. Summitter's identification :**

a. MORIA  
15 rue Georges Besse  
92160 ANTONY  
FRANCE

b. Contact person : Alain DUPRAT  
Chief Executive Officer



c. Date Summary Prepared : May, 15th, 1998

**2. Device name :**

Trade Name : CARRIAZO BARRAQUER microkeratome

**3. Classification name :**

Microkeratome

**4. Substantial equivalence :**

Substantial equivalence is being claimed to the following legally marketed devices

a. Company : PLANCON INSTRUMENTS  
Device : PLANCON microlamellar keratome  
EVOLUTION power unit  
510 (K) : K 980 924

b. Company : HANSA Research & Development  
Device : Automatic corneal shaper  
510 (K) : K 913 697

c. Company : HANSA Research & Development  
Device : Hansatome  
510 (K) : K 972 808

## 5. Device description

### System composition

- a) Power unit
- b) Keratome head
- c) Keratome blade
- d) Motor
- e) Footswitches
- f) Applanator lenses
- g) Suction rings

#### a) 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 :
  - DC motor outlet,
  - Gas inlet,
  - Gas outlet,
  - Vacuum outlet,
  - Foot pedals,
  - Battery charger.

All connectors are of different type for preventing connecting mistakes.

**b) Keratome motor**

**Option 1 : Turbine motor**

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.

**Option 2 : Electrical 12 V DC motor**

**c) Keratome head**

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

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

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

**d) Suction rings**

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

The disks are mounted on the suction handle by means of a threaded tube welded on the ring.

**e) Applanator lenses**

The applanator lenses are made of clear methylnmethacrylate with a stainless steel handle.

They are used with the rings to control disk diameter before the cut.

The upper face is convex for magnification.

The base face (contact face) is plano, with an engraved and calibrated reticle diameter.

**6. Statement of intended use**

The CARRIAZO BARRAQUER microkeratome 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 CARRIAZO BARRAQUER keratome 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.



JUL 24 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K981741  
Trade Name: CARRIAZO BARRAQUER microkeratome  
Regulatory Class: I  
Product Code: 86 HMY  
Dated: July 1, 1998  
Received: July 6, 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

MORIA  
CARRIAZO BARRAQUER microkeratome

May 15, 1998  
Premarket Notification  
Section 4 page 1

510(k) Number (if known) :

**Device Name :**

CARRIAZO BARRAQUER microkeratome

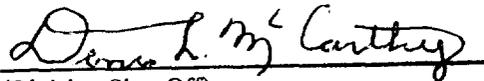
**Indications for use :**

The CARRIAZO BARRAQUER microkeratome 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K981741

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)