

SEP 24 1999

K992687

8-1

## 8. 510(k) Summary.

### 8.1. Submitter's identification.

- Industrial & Medical Design, Inc.  
6230 Wilshire Blvd., Suite 410  
Los Angeles, CA 90048
- Contact person: Yevgeniy Kuklin  
President
- Date Summary Prepared: July 15, 1999

### 8.2. Submitted device name.

- Trade name: Millenium Microkeratome
- Classification name: Keratome

### 8.3. Identification of predicate device.

- Company: Plancon Instruments  
Device: Plancon microlamellar keratome  
Evolution power unit  
510(k) K980924
- Company: Plancon Instruments  
Device: Plancon microlamellar keratome  
510(k) K970377

### 8.4. Device description.

Millenium Microkeratome is electrically powered manual mechanical cutting instrument for severing a thin layer of corneal tissue (flap) from the surface of the eye. Microkeratome includes Fixation Ring, cutting Head and operates by Control Unit. The Fixation Ring is placed against the eye. Cutting blade oscillate inside special Insert placed in to the Head. Electric Motor is used to drive the blade. Forward manual movement of the Head against Fixation Ring creates resection of cornea tissue. Different Fixation Rings and Inserts determinate diameter and thickness of resection. Control Unit - power independent with built-in rechargeable battery provide vacuum to hold Fixation Rind on the eye and electric power to control Electric Motor.

## 8.5. Intended use of the device.

Millenium Microkeratome is intended for use in refractive surgery, or other treatment requiring initial lamellar resection of the cornea, circular and predetermined diameter and thickness.

## 8.6. Comparative technological characteristics of submitted and predicate devices.

Parameter	Plancon Instruments : K970377	Plancon Instruments : K980924	Submitted device
Indication for use	To perform microlamellar keratoplasty	To perform microlamellar keratoplasty	To perform initial resection of the cornea
Operation principle	Gas turbine driven oscillating blade. Manual movement of the keratome head.	Gas turbine driven oscillating blade. Manual movement of the keratome head.	Electric motor driven oscillating blade. Manual movement of the keratome head.
Safety test function	None	Self-checking. Efficiency of pumps, input pressure and pressure applied to the turbine check.	Self-checking. Efficiency of the pump, battery charge level, and rotation speed of the electric motor check.
System composition	Control unit Turbine motor Fixed keratome head Keratome blade Fixation ring Applanation lenses	Control unit Turbine motor Fixed keratome head Keratome blade Fixation ring Applanator lenses	Control unit Electric motor Adjustable keratome head Keratome blade Fixation ring Applanator lens
Control unit	Vacuum pump. Vacuum release valve. Gas regulator. Gas & vacuum gauges. Vacuum & turbine quick connectors. Rechargeable battery.	Two vacuum pumps Vacuum release valve. Gas regulator. Gas & vacuum sensors. LED display Vacuum & turbine quick connectors. Rechargeable battery.	Vacuum pump. Vacuum release valve. Electric motor controller Vacuum sensors and rotation speed control. LED display Vacuum & electrical quick connectors. Rechargeable battery.

Keratome motor	: Gas powered. : Adjustable speed up : to 20,000 RPM : (recommended : 14,000 RPM).	: Gas powered. : Adjustable speed up : to 20,000 RPM : (recommended : 14,000 RPM).	: Electric motor. : Adjustable speed up : to 28,000 RPM : (pre-set 14,000RPM).
Keratome head	: Fixed single piece : head. Depth of cut : depends on the head : modification. : Stainless steel	: Fixed single piece : head. Depth of cut : depends on the head : modification. : Stainless steel	: Fixed Base and different : Inserts to produce : predetermined depth : of the cut. : Stainless steel

### 8.7. Discussion of tests and results.

The specifications and intended use of Millenium Microkeratome are the same or very similar to predicated devises. Non-clinical testing on porcine eyes was found to result in corneal lamellar resection equivalent to predicated devices. Therefore, the technological differences between Millenium Microkeratome and predicated device do not raise any new issues of safety, effectiveness, or performance of the product.



SEP 24 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Yevgeniy Kuklin  
President  
Industrial & Medical Design, Inc.  
6230 Wilshire Blvd., Suite 410  
Los Angeles, CA 90048

Re: K992687  
Trade Name: Millenium Microkeratome  
Regulatory Class: II  
Product Code: 86 HMY  
Dated: September 10, 1999  
Received: September 13, 1999

Dear Mr. Kuklin:

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.

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This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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 at (301) 443-6597.

Sincerely yours,



A. Ralph Rosenthal, M.D.  
Director  
Division of Ophthalmic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**5. Indication for Use Statement.**

Applicant: Industrial & Medical Design Inc.

510(k) Number: K992687

Device Name: Millenium Microkeratome.

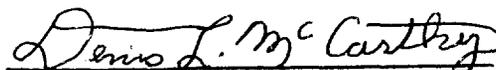
Indications for Use:

Millenium Microkeratome is indicated for use in refractive surgery, or other treatment requiring initial lamellar resection of the cornea, circular and 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 K992687

Prescription Use X  
(Per 21 CFR 801.109)

OR

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