

APR 15 1998

K980924

510 K SUBMISSION  
PLANCON INSTRUMENTS  
15 RUE GEORGES BESSE - 92160 ANTONY - (FRANCE)

**Re. :**  
**510 K submission**  
**Safety and effectiveness summary**

Dear Sirs,

I certify that I have conducted a reasonable search of information known or otherwise available to me about the types and causes of safety and/or effectiveness problems that have been reported for the Keratome. I further certify that I am aware of the types of problems to which the Keratome is susceptible and that the following summary of the types and causes of safety and/or effectiveness problems about the Keratome is complete and accurate :

<b>Problems reported for the Lamellar Keratoplasty and causes</b>	
<b>Problem</b>	<b>Causes</b>
Machine performance	Quality of maintenance and cleaning procedure
Wrong assembly	Forgetting pieces or not following the check-list
Poor centration of the cut	Poor centration of the suction ring on the eye
Poor cut quality	Insufficient I.O.P., Poor suction
Poor suction	Conjunctival chemosis due to retrobulbar anesthesia
Debris at the interface or epithelial cell proliferation at the interface	Insufficient sweeping of bed and cap
Loss of flap during operation	Flap not stored on moist chamber
Microkeratome incision too deep (perforation) or too shallow (corneal flap incomplete)	Incorrect setting and checking of the Keratome Incorrectly assembled Keratome
Wound infection	Sterility / cleaning more stringent than for other surgeries
Excessive I.O.P. or vascular occlusion	Excessive vacuum level
Irregular / incomplete cut	Poor blade's quality

### ***Safety and effectiveness analysis***

The microlamellar Keratoplasty has been evolving from nearly 20 years. The problems associated with this surgery and devices are well known. They can be classified as follows :

1) Problems related to instrument assembly and in particular Keratome head assembly :

- Blade assembly (problem cancelled with submitted device)
- Blade holder assembly (problem cancelled with submitted device)
- Mounting of the head on the turbine

2) Problems related to instrument setting and checking :

- Cut depth (problem cancelled with new device),
- Vacuum level,
- Blade quality

3) Problems related to poor maintenance, cleaning and sterilization :

- Disassembling (problem cancelled with new device),
- Cleaning,
- Sterilizing.

4) Problems related to the surgical procedure.

Same as filed submitted for 510 K document number K 960395 and K 970377.

Printed name of person required to submit 510 (k) : Alain DUPRAT

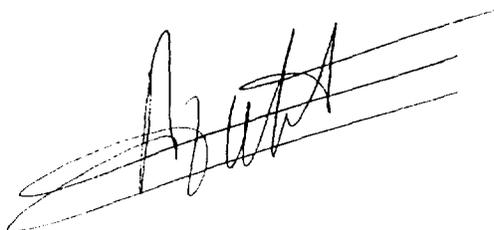
Signature of person required to submit 510 (k) :

Title of person submitting 510 (k) : General Manager

Name of Company : PLANCON INSTRUMENTS

Date : March 10th, 1998

Sincerely yours.

A handwritten signature in black ink, appearing to read 'Alain Duprat', is written over a set of three horizontal lines. The signature is stylized and somewhat cursive.

**SAFETY AND EFFECTIVENESS SUMMARY**

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	Predicated device ① 510 K Document number K 960395	Predicated device ② 510 K Document number : K 970377	Submitted device
Designation / Feature	PLANCON INSTRUMENTS	PLANCON INSTRUMENTS	PLANCON INSTRUMENTS
Intended use	To perform microlamellar keratoplasty for the correction of myopia or hyperopia	To perform micro lamellar keratoplasty for the correction of myopia or hyperopia	To perform microlamellar keratoplasty for the correction of myopia or hyperopia
System composition	Power unit Turbine motor Adjustable keratome head Keratome blade Pneumatic fixation rings Applanation lenses Plate checking gauge	Power unit Turbine motor Adjustable keratome head Keratome blade Pneumatic fixation rings Applanation lenses Plate checking gauge	Power unit Turbine motor Fixed keratome head Keratome blade Pneumatic fixation rings Applanation lenses
Power unit	Vacuum pump Battery Vacuum release valve Knob to regulate gas pressure Gas & vacuum pressure gauges Vacuum & turbine quick connectors Battery charger unit	Vacuum pump Battery Vacuum release valve Knob to regulate gas pressure Gas & vacuum pressure gauges Vacuum & turbine quick connectors Battery charger unit	Vacuum pump Battery Vacuum release valve Knob to regulate gas pressure Gas & vacuum pressure gauges Vacuum & turbine quick connectors Battery charger unit
Power unit functions	See document attached		

	Predicated device ① 510 K Document number K 960395	Predicated device ② 510 K Document number : K 970377	Submitted device
Designation / Feature	PLANCON INSTRUMENTS	PLANCON INSTRUMENTS	PLANCON INSTRUMENTS
Turbine motor	Gas powered Adjustable speed 0 to 20 000 RPM (recommended 14 000 RPM) Material : stainless steel, titanium and aluminium. No gear system	Gas powered Adjustable speed Material : stainless steel No gear system	Gas powered Adjustable speed 0 to 20 000 RPM (recommended 14 000 RPM) Material : stainless steel, titanium and aluminium. No gear system
Keratome	Material : stainless steel Adjustable Safety : maximum cut depth, and checking gauge	Material : stainless steel Adjustable Permanent adjustable head with adjustment knob Safety : maximum cut depth and checking gauge	Material : stainless steel Fixed single piece head Safety : only one cut depth allowed by head principle
Pneumatic fixation rings	Material : stainless steel Double dovetails	Material : stainless steel Double devetails	Material : stainless steel Double dovetails
Applanation lenses	Material : clear plastic + stainless handle Engraved inner reticle diameter	Material : clear plastic + stainless handle Engraved inner reticle diameter	Material : clear plastic + stainless handle Engraved inner reticle diameter

**SAFETY AND EFFICIENCY SUMMARY  
POWER UNIT FUNCTIONS AND SAFETY FEATURES**

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FUNCTION / SAFETY FEATURES	PREDICATED DEVICES K 96 03 95 K 97 03 77	SUBMITTED DEVICE
1) Vacuum level gage	Indicator by needle	Liquid cristal display
2) Turbine pressure gage	Indicator by needle	Liquid cristal display
3) Unsuufficient vacuum indicator	None	Red LED and audible tone indicating usufficient vacuum level
4) Wrong turbine pressure indicator	None	Red LED and audible tone indicating uncorrect pressure setting
5) Battery charge indicator	Indicator by needle gage	Indication by LEDS green and red
6) Vacuum connector	LUER lock type	LUER lock plus a safety lock plate to prevent undesired unplugging
7) Turbine connector		No change, identical to approved device
8) Tank input pressure indicator	None	Visible indicator in case of unsufficient nitrogen pressure supply
9) Main switch		No change, identical to approved device
10) Dual level vacuum function	None	The vacuum level can be decreased from 150 mmHg to 600 mmHg by means of a switch. A LED indicator is « ON » when low vacuum is selected. This function allows the surgeon to hold the eye after the surgery with a much softer vacuum level.
11) Battery	1 battery of 12 volts Capacity : 6 Ah	1 batterie of 12 volts Capacity : 12 Ah for higher autonomy
12) Vacuum pump	1 vacuum pump	2 vacuum pumps The second acts as a back up in case of loss of vacuum detected by a built in monitoring system
13) Battery charge		No change, identical to approved device
14) Pedal No		No change, identical to approved device
15) Nitrogen supply connector		No change, identical to approved device
16) Test function	None	The unit has a self checking function operated by depressing a switch. This function will check the efficiency of the 2 pumps, the nitrogen supply pressure and the ajustement of pressure to the turbine. The unit can only be operated if the test is passed. If test is not passed, blinking and audible signals indicate why test is not passed.
17) Dry chamber	Single cavity dry chamber	Double cavity dry chamber for increased prevention of fluid to be aspirated by the pumps.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 15 1998

Mr. Alain Duprat  
General Manager  
PLANCON INSTRUMENTS  
15 Rue Georges Besse  
Antony, France

Re: K980924  
Trade Name: Plancon Microlamellar Keratome-Evolution power unit  
Regulatory Class: I  
Product Code: 86 HNO  
Dated: January 8, February 11, and March 10, 1998  
Received: January 11, February 14, and March 12, 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 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.

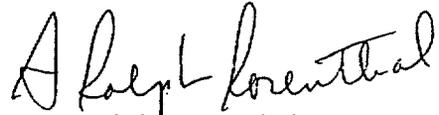
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Alain Duprat

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) : K980924

**Device Name :**

Plançon Microlamellar Keratome - **EVOLUTION** power unit.

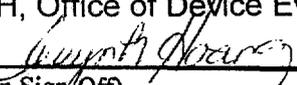
**Indications for use :**

This device is intended for use in refractive surgery, to perform microlamellar keratoplasty or keratomileusis in-situ for the correction of myopia and hyperopia.

(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 K980924

Prescription Use X  
(Per 21 CFR 801.109)

OR

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