K974243

510K Summary
Insight Technologies Instruments, LLC.
Model K-1000 Keratome System

JAN 20 1998

Insight Technologies Instruments, LLC.
16 Higgins Drive
Milford, CT 06460
Tel: 203-874-1832
Fax: 203-877-3762

Submitters Name: Charles Vassallo — Charles Vassallo

22 Dec 97 — Date

Ref: 510K Premarket Notification

To: Document Control Clerk:

This summary of 510K safety and effectiveness information is being submitted for the Insight Technologies Instruments, Model K-1000 Keratome, which an equivalence determination could be based.

Trade/Proprietary Name: Model K-1000 Keratome System

Common/Usual Name: Keratome

Classification Name: Keratome

Establishment Registration Number: In process at FDA

Performance Standard:

Designed and tested following the suggested guidelines ANSI/AAMI ES1-1993. The low frequency leakage currents are well within the safe current limits for electromedical apparatus.

The Insight Technologies Instruments, LLC, Model K-1000 Keratome is simular in design construction, and function to the devices as marketed by:

- Plancon Instruments,
  ANTONY FRANCE 92160
  Lamellar Keratoplasty System
  Model L.K.S.
  Reference 510k: K970377

- S.C.M.D. Keratomes of Arizona,
  FTN. HILLS, AZ 85268
  TurboKeratome System by SCMD
  Model MLK
  Reference 510k: K935342

Descriptive Comparison:

Refer to "Attachment 1" for similarities and differences between the Insight Technologies Instruments LLC, Model K-1000 and the above predicated instruments.

Characteristics:

The model K-1000 keratome features a high speed, low torque nitrogen driven motor, which drives a reciprocating surgical blade. The blade will be a single-use, disposable device that will be filed under a separate 510k. The keratome head is preset to produce a corneal resection approximately 160 microns in depth with the corresponding blade insertion and flap diameter of approximately 10.0mm.

The model K-1000 keratome system is battery operated and may also operate from its charger. The power unit provides on/off footswitch controls for the keratome head and drive assembly, and suction to the suction ring. Analog gauges located on the front panel of the unit indicate *nitrogen pressure* and *suction level* supplying the appropriate connectors.

Certification of Standards:

Insight Technologies Instruments certifies that the model K-1000 keratome will be manufactured according to ANSI/AAMIES1-1993 "American National Standard for Electrical Safety" standard. It will also follow guidelines set by IEC 601-1, "Medical Electrical Equipment".

Certification of Safety and Effectiveness:

When used according to the manufacturers' instructions, there are no adverse safety indications for the model K-1000 keratome.

Components that come in direct contact with tissue are made of surgical stainless steels commonly found in other surgical devices. These components can be steam sterilized using gravity displacement at 25C degrees for 30 minutes

Directions for Use:

Insight Technologies Instruments will enclose an operator's manual with every system. The power unit stenciling is located on the front and rear panels identify the system indicators, controls, fuse, and connectors. Affixed to the rear panel will be a self-stick label identifying the input power requirements, model number, part number, and serial number.

Labeling:

The head and drive assembly labeling will consist of the company logo. The individual footswitches will be identified with a self-stick label.

Sterilization Methodology:

The user can sterilize the keratome head, turbine, stop ring, and suction ring using steam.

"Attachment 1"

Comparison Chart
Insight Technologies Instruments, LLC.
Model K-1000 Keratome System

Characteristic	ITI Model K-1000	Plancon	S.C.M.D.
Turbine:	Nitrogen Gas	Nitrogen Gas	Nitrogen Gas
Oscillatory Speed:	14,000 rpm	14,000 rpm	14,000-20,000 rpm
Blade Direction:	Oscillatory Sideways	Oscillatory Sideways	Oscillator Sideways
Blade Angle	25°	25°	25°
Suction Ring:	Single, 10.0mm	3.5 to 10.5mm	3.5 to 10.5mm
Console Dimensions:	11 x 9 x 8 inches (28 x 23 x 20cm)	11.8 x 9.3 x 6.3 inches (30 x 23.5 x 16cm)	15 x 18 x 9 inches (38 x 46 x 23cm)
Console Weight:	20lbs (9kg)	18lbs(8kg)	19lbs (kg)
Mains Power Protection:	3.15 amp, slo-blo fuse	none	none
Input Voltage:	12 volts DC	12 volts DC	12 volts DC
Charger:	110 volts AC @ 60 Hz	110 volts AC @ 60 Hz 100 volts AC @ 60 Hz	110 volts AC 60Hz

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 1998

Mr. Charles Vassallo
Insight Technologies Instruments
16 Higgins Drive
Milford, CT 06460

Re: K974243
Trade Name: Model K-1000 Keratome System
Regulatory Class: I
Product Code: 86 HMY
Dated: November 10, 1997
Received: November 12, 1997

Dear Mr. Vassallo:

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

Indications for Use

Insight Technologies Instruments, LLC.
Model K-1000 Keratome System

510(k) Number (if known): _____

Device Name: Model K-1000 Keratome System

The Insight Technologies Instruments, Model K-1000 Keratome System is designed to produce a corneal flap.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Denise L. McCarthy

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number _____

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