K970088

JAN - 9 1998

F: 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY

1)	Submitter:	Iotec Industries™ 7538 Pebble Drive Fort Worth, TX 76118 Phone No.: (817) 589-3799
	Contact Person:	Roger Cooper Executive Vice President Regulatory Affairs
	Date Prepared:	Monday, 3 March 1997
2)	Name of Device:	Iotec Trocar and Flexible Cannula
	Common Name:	Trocar and Flexible Cannula
3)	Predicate Device:	Access Surgical Intl. Inc. K940587 Ethicon, Inc. K931111
4)	Description of Device:	The Iotec Trocar and Flexible Cannula is composed of Plastic, Stainless Steel (or plastic rod) for attachment of the trocar tip; and a flexible plastic cannula tube.
5)	Intended Use:	The intended use of this device is to create a point of entry for endoscopic instruments into the abdominal and chest cavities during a endoscopic procedure. The Cannula is flexible to accommodate curved instruments.

6) Technological characteristics of this device are comparable to the predicate device in that predicate device is also used to create a point of entry for endoscopic instruments into the abdominal cavity during a endoscopic procedure.

SECTION G:

MANUFACTURER'S STATEMENT OF SUBSTANTIAL EQUIVALENCE

(To be provided with 510(k) notification for tier 2 devices)

STATEMENT OF INDICATIONS FOR USE: The product is intended to create a point of entry for curved endoscopic instruments into the abdominal and chest cavities during a endoscopic procedure.

CLAIMS: Creates a point of entry for straight and curved endoscopic instruments into the abdominal and chest cavities.

This notification contains all of the information required by 21 CFR 807.87.
A completed copy of the "DRAERD Premarket Notification 510(k) Reviewer's Screening Checklist" is attached.

The subject device conforms to the following voluntary and mandatory standards:
There are no existing performance standards available.

The subject device has the same technological characteristics as a legally marketed predicate device. Specifically, the features, specifications, materials, and mode of action are equivalent. If the subject device is a kit, all of the contents of the kit are either pre-Amendment devices or have been cleared for marketing through previous 510(k)s. The kit contains no drug or biologic products.

The above statements are accurate representations of this 510(k) premarket notification and of the device this firm intents to market. All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted (21 CFR 807.87(J)).

MANUFACTURER: Iotec Ind.

OFFICIAL CORRESPONDENT: _____ (signature)

Roger Cooper (printed name)

TITLE: Executive Vice President - Regulatory Affairs

DATE: 3 March 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James Lutkenhaus
Quality Assurance Regulatory
Iotec Industries™
P.O. Box 821834
North Richland Hills, Texas 76182

JAN - 9 1998

Re: K970888
Trade Name: Iotec Trocar and Flexible Cannula
Regulatory Class: II
Product Code: GCJ
Dated: November 25, 1997
Received: December 2, 1997

Dear Mr. Lutkenhaus:

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) 594-4595. 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K970888

Device Name: Iotec Trocar and Flexible Cannula

Indications For Use:
The product is intended to create a point of entry for curved endoscopic instruments into the abdominal and chest cavities during a endoscopic procedure.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970888

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)