K040855

APR 1 6 2004

Summary of Safety and Effectiveness

1.	**Submission Applicant & Correspondent**
	Name: Instrumed International, INC. Address: 626 Cooper Court Schaumburg, IL 60173 Phone: 847-908-0292 Fax: 847-908-0293 Mail: jwalsh@instrumedinc.biz Contact person: Jim Walsh
2.	**Device name & Classification panel**
	Trade name: Laparoscope & Monopolar laparoscopic instruments Common name: Laparoscope & Accessories Classification: 876.1500
3.	**Substantial Equivalence**
	Substantial Equivalence is claimed to the following devices Gimmi Laparoscope Manufactured by Gimmi GmbH Registered in the FDA Database under the following number: **K012660**

4.	Description of device
	Instrumed Laparoscopes provide illumination and visualization in diagnostic procedures and in conjunction with laparoscopic instruments (accessories) operative laparoscopic procedures

5.	Intended Use & Indications
	Instrumed Laparoscopes and Accessories are intended to be used by qualified physicians to provide access, illumination and visualization of internal structures and for manipulating soft tissue (grasping, cutting, coagulating, dissecting, and suturing) in a wide variety of diagnostic and therapeutic laparoscopic/urologic closed and minimally invasive procedures.

6.	Technical Comparison
	The Instrumed product is similiar to the Gimmi product in terms of design and technical characteristics. The Laparoscope and the respective laparoscopic instruments are identical to the Gimmi products. The Instrumed product is also similiar to the Gimmi products in terms of the used material. In terms of performance data, the presented data that was conducted on the Instrumed instruments shows in its results that the Laparoscope and the laparoscopic instruments are absolutely safe and effective for its intended use and do not raise any questions regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 6 2004

Instrumed International, Inc.
c/o Mr. Stefan Preiss
TÜV America, Inc.
1775 Old Highway 8
New Brighton, Minnesota 55112

Re: K040855
Trade/Device Name: Instrumed Laparoscopes and Accessories
Regulation Number: 21 CFR 878.4400, 876.1500
Regulation Name: Electrosurgical cutting and coagulation device and accessories; Endoscope and accessories
Regulatory Class: II
Product Code: GEI, GCJ
Dated: March 25, 2004
Received: April 2, 2004

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

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

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Instrumed Laparoscopes and Accessories

Indications for Use:

Instrumed Laparoscopes and Accessories are intended to be used by qualified physicians to provide access, illumination and visualization of internal structures and for manipulating soft tissue (grasping, cutting, coagulating, dissecting, and suturing) in a wide variety of diagnostic and therapeutic laparoscopic/urologic closed and minimally invasive procedures.

Mark N Milliken

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040855

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)