DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 1999

Jakoubek Medizintechnik GmbH
c/o Mr. Douglas Hulfish
Life Med Technology
1822 N. Stratford Road
Arlington Heights, Illinois 60004

Re: K990785
Trade Name: Trocar and Trocar Sleeves, Laparoscopes,
Laparoscopic Forceps and Laparoscopic Instruments
Regulatory Class: II
Product Code: GCJ and GEI
Dated: June 30,1999
Received: July 2, 1999

Dear Mr. Hulfish:

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 requirement, 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,

for Mark N Melkerson

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): K990785

Device Name: SUCTION/IRRIGATION CANNULAE

Indications For Use:

Providing thorough irrigation and aspiration of the peritoneal cavity.Bleeders can be identified,bile,stones,tissue,blood & smoke from cautery procedures can be aspirated leaving the abdominal cavity clean and dry.

Mark N Milhouse

for (Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990785
1 of 8

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

510(k) Number (if known): K990785

Device Name: FAN RETRACTORS AND FINGER DISSECTORS

Indications For Use:

Sole purpose of these instruments are to move tissue around. They can not grasp or restrain by means of grasping any body organ or tissue. They are introduced into the body cavity through a trocar sleeve. Once introduced they can only move tissue from side to side or up and down.

Mark N Milhersan

for (Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990785

2 OF 8

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

510(k) Number (if known): K990785

Device Name: TROCARS, TROCAR SLEEVES AND DILATORS

Indications For Use:

Devices which create portals into an operative site enableing the introduction thru said devices, tools for the direct observation and/or dissecting, cutting, repairing, removal or manipulation of internal tissues and/or organs.

Mark N Milkerson

for (Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990785

3 OF 8

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

510(k) Number (if known): K990785

Device Name: LAPAROSCOPES

Indications For Use:

Devices that pass thru portals into a periteal cavity allowing direct or indirect visualization by means of a camera thru said device. Internal tissues or organs may be visualized for either diagnostic or operative procedures.

Mark N Milhoussen

for (Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990785

4 of 8

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

510(k) Number (if known): K990785

Device Name: VERRES NEEDLES

Indications For Use:

Verres needles puncture through the abdominal wall to enable the introduction of gases into theabdominal cavity creating space between the fascia and the internal body organs,allowing for the safe introduction of laparoscopic instrumentation into the peritoneal cavity.

for Mark N Milhern

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990785
5 OF 8

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

510(k) Number (if known): K990785

Device Name: KNOT PUSHER

Indications For Use:

Instruments which permit suturing internal tissues or organs thru cannula portals by pushing suture knots down to the tissue site being repaired.

Mark N Milhausen

for (Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990785
6 of 8

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

510(k) Number (if known): K990785

Device Name: NEEDLE HOLDERS

Indications For Use:

Instruments which permit the grasping and manipulation of needles inside the peritoneal cavity enableing a surgeon to suture internal tissues during laparoscopic procedures.

Mark N Milhoan

for (Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990785 7 of 8

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

510(k) Number (if known): K990785

Device Name: MONOPOLAR ELECTRODES, CAUTERY FORCEPS, BIPOLAR FORCEPS & SCISSORS AND NON-CAUTERY FORCEPS

Indications For Use:

Instruments insulated for cautery or non-insulated for non-cautery procedures which enable a surgeon to grasp, biopsy, cut, coagulate, manipulate or retrieve internal tissues or organs while performing laparoscopic procedures.

Mark N Milbern

for (Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990785
8/01/8

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)