

JUL 12 1999

OLYMPUS WINTER & IBE

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K 990237
510(k) SUMMERY

OLYMPUS TROCAR SYSTEM ACC. TO HASSON

This summery of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Device Name: Trocar System according to Hasson.

Common/Usual Name: Trocar, blunt and cone for laparoscopic application.

Classification Name: LAPAROSCOPE, GENERAL & PLASTIC SURGERY
and LAPAROSCOPE, GYNECOLOGIC (AND ACCESSORIES)

Classification: CFR 876.1500 Class II
and CFR 884.1720 Class II

Predicate Devices:

Manufacturer	Description	510(k)
Olympus	A5676 11 mm Trocar Tube, 125 mm	K923982
	A5673 11 mm Trocar, 225 mm, Conical tip	K923982
	O5203 Trocar 11 mm, with valve and conical tip	K790071
Karl Storz	30103 GO Trocar, size 11 mm, consisting of:	Unknown
	30103 O Trocar only, with blunt tip	
	30103 G Cannula, 2 flanges for fixation with sutures, adjustable conical sleeve, insufflation stopcock, for 10 mm laparoscopes, length 13 cm	
Karl Storz	30160 C1 Cone for trocars size 6 mm, black	Unknown
	30101 C1 Cone for trocars size 7 mm, black	
	30103 C1 Cone for trocars size 11 mm, black	
	30101 C1 Cone for trocars size 13 mm, black	

**Prepared & Submitted by:
(Contact Person)**

Mrs. Laura Storms-Tyler
Olympus America Inc.
Endoscope Division
Two Corporate Center Drive
Melville, NY 11747-3157
Phone: 516-844-5688
FAX: 516-844-5416

Summery Preparation Date: November 30, 1998

Statement of Intended Use:

The Olympus „Trocar System according to Hasson“ has been designed for first puncture technique according to Hasson in laparoscopic application.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 1999

Ms. Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America, Inc.
Two Corporate Center Drive
Melville, New York 11747

Re: K990237
Trade Name: Trocar System According to Hasson
Regulatory Class: II
Product Code: GCJ
Dated: April 8, 1999
Received: April 21, 1999

Dear Ms. Storms-Tyler:

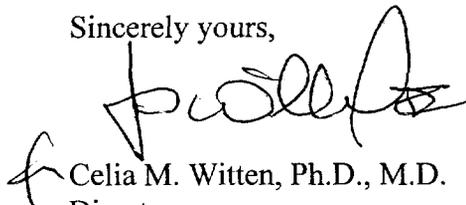
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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

K 990 237

510(k) Number (if known):

Device Name: Trocar System according to Hasson

Indications for Use:

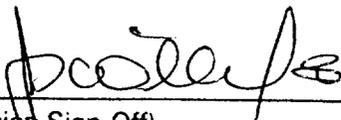
The Olympus „Trocar System according to Hasson“ has been designed for first puncture technique according to Hasson in laparoscopic applications.

(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 21CFR 801.109)

(Optional Format 1-2-96)


(Division Sign-Off)
Division of General Restorative Devices K990237
510(k) Number _____