

OLYMPUS WINTER & IBE

Business address: Kuehnestr. 61 • D-22045 Hamburg
 Mailing address: Postfach 70 17 09 • D-22017 Hamburg
 Tel: (040) 6 69 66-0 • Telefax: (040) 6 68 15 91

K 984417

510(k) SUMMARY

OLYMPUS BIPOLAR FORCEPS

This summary 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: Bipolar Grasping Forceps BiQ⁺
Common/Usual Name: Bipolar Forceps
Classification Name: DEVICE, ELECTROSURGICAL, CUTTING & COAGULATION & ACCESSORIES.
Classification: CFR 878.4400 Class II

Predicate Devices:

Manufacturer	Description	510(k)
Everest Medical Corp.	BiCOAG [®] Bipolar Dissecting Forceps	K945975 K955001 K971565
Olympus	A5380, A5382 Bipolar forceps, Ø5 mm, micro tweezers	K955623
Olympus	A5384, A5386 Bipolar forceps, Ø5 mm, tweezers, thin	K955623
Olympus	A5388, A5390 Bipolar forceps, Ø5 mm, tweezers, thick	K955623
Olympus	A5392, A5394 Bipolar forceps, Ø5 mm, Hirsch	K955623
Olympus	A6124, A6322 HiQ Handinstruments	K944201

Prepared & Submitted By: Mrs. Laura Storms-Tyler
 (Contact Person) Olympus America Inc.
 Endoscope Division
 Two Corporate Center Drive
 Melville, NY 11747-3157
 Phone: 516-844-5688
 Fax: 516-844-5416

Summary Preparation Date: February 16, 1999

Statement of Intended Use:

The Olympus Bipolar Forceps has been designed for grasping and coagulation of soft tissue and blood vessels during endoscopic treatment in laparoscopic and gynecological applications.



FEB 24 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America, Inc.
Two Corporate Center Drive
Melville, New York 11747-3157

Re: K984417
Trade Name: OLYMPUS Bipolar Forceps BiQ⁺
Regulatory Class: II
Product Code: GEI
Dated: November 26, 1998
Received: December 10, 1998

Dear Ms. Storms-Tyler:

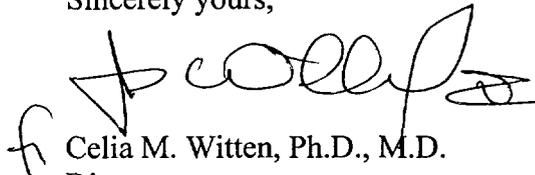
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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): K 984417

Device Name: OLYMPUS Bipolar Forceps BiQ⁺

Indications for Use:

The Olympus Bipolar Forceps has been designed for grasping and coagulation of soft tissue and blood vessels during endoscopic treatment in laparoscopic and gynecological applications.

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

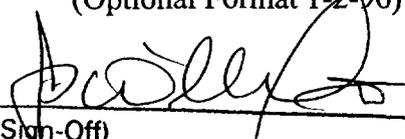
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(per 21CFR 801.109)

OR

Over-the Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984417