

MAR 12 2003

**510(k) SUMMARY**

K 024 138

**OLYMPUS Heat scissors generator set and  
Heat scissors handpiece**

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

**A. Submitter's Name, Address, Phone and Fax Number**

**1. Manufacturer of the subject device**

Name & Address of Manufacturer;	Olympus Optic-Electronics Co., Ltd. Aomori Plant 248-1 Okkonoki 2-chome Kuroishi-shi Aomori, Japan, 036-0367
Registration No:	9614641
Address, Phone and Fax Number of R&D Department of Endoscope Division	2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan TEL 81-426-42-2891 FAX 81-426-46-2291

**2. Name of Contact Person**

Name :	Ms. Laura Storms-Tyler Director, Regulatory Affairs Olympus America Inc.
Address, Phone and Fax	Olympus America Inc. Two Corporate Center Drive Melville, NY 11747-3157 TEL (631) 844-5688 FAX (631) 844-5416

**B. Device Name, Common Name**

**1) Heat scissors generator set**

1. Device Name:	Heat scissors generator
2. Common/Usual Name:	Heat scissors generator
3. Classification:	Electrosurgical Cutting & Coagulation Device & Accessories 21 CFR 878.4400

**2) Heat scissors handpiece**

1. Device Name:	Heat scissors handpiece (XRF-940-M)
2. Common/Usual Name:	Heat scissors handpiece
3. Classification:	Electrosurgical Cutting & Coagulation Device & Accessories 21 CFR 878.4400

**C. Predicate Devices :**

<b>Model</b>	<b>Device Description &amp; 510(k)#/ Date of Cleared</b>	<b>Manufacturer</b>
HPU-20	#K982289	Olympus Optical Co., Ltd.
Shaw II SURGERY SYSTEM	#K902307	HENOSTATIC SURGERY CORP.
THERMAL CAYTERY DEVICE, FORCEPS	#K990728	STARION INSTRUMENTS

**D. Summary Description of the Device**

**1. Summary**

The Heat scissors system has been designed to cut and coagulate tissue for general (open) abdominal surgery. This system consists of the Heat scissors generator, Heat scissors handpiece and foot switch. This system uses direct thermal energy and simultaneous pressure to cut and coagulate tissue. The thermal energy is generated at the Heat-generating section of the blade, on the Heat scissors handpiece. It is conveyed via a non-stick coating on the blade to the tissue.

**2. Design**

“Heat scissors system” has been designed, manufactured and tested in compliance with voluntary safety standards. It meets the requirements of IEC 60601-1 and IEC60601-1-2.

**3. Materials**

The biocompatibility test reports of the above new materials show that such materials complies with ISO 10993-1.

**E. Intended Use of the device**

- Heat scissors generator set

Heat scissors generator has been designed to generate electrical energy to the Heat scissors handpiece to cut and coagulate body tissue.

- Heat scissors handpiece (XRF-940-M)

The Heat scissors handpiece has been designed to cut and coagulate body tissue in general(open) abdominal surgery.

**F. Reason for not requiring clinical data**

When compared to the predicate devices, “Heat scissors system ” does not incorporate any significant difference for safety and efficacy to the predicate devices.

Therefore, clinical data is not necessary for its evaluation of its safety and efficacy.



MAR 12 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Olympus Optic-Electronics Company, Ltd  
c/o Ms. Laura Storms-Tyler  
Director, Regulatory Affairs  
Olympus America, Inc.  
Two Corporate Center Drive  
Melville, New York 11747-3157

Re: K024138

Trade/Device Name: Heat Scissors System  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II  
Product Code: GEI  
Dated: December 13, 2002  
Received: December 16, 2002

Dear Ms. Storms-Tyler:

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.

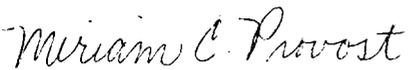
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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 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

510(k) Number(if known): ~~Not assigned yet~~ K 0 2 4 1 3 8

Device Name: Heat scissors system

(Heat scissors generator set and Heat scissors handpiece)

**Indications for Use:**

**-Heat scissors generator set**

The Heat scissors generator set has been designed to generate electrical energy to the Heat scissors handpiece to cut and coagulate body tissue.

**-Heat scissors handpiece (XRF-940-M)**

The Heat scissors handpiece has been designed to cut and coagulate body tissue in general (open) abdominal surgery.

Miriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K 0 2 4 1 3 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)

(Optional Format 1-2-96)