DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 6 1999

Olympus Optical Company, Ltd.
Mr. James R. Veale
Vice President, Regulatory Services
c/o Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K982133
Trade Name: Olympus Endoscopic Systems for Lumbar Hernia Discectomy
Regulatory Class: II
Product Code: HRX and KOG
Dated: August 27, 1998
Received: August 28, 1998

Dear Mr. Veale:

This letter corrects our substantially equivalent letter of October 22, 1998 regarding the regulatory classification of your device, which is changed from HRZ to HRX. This device is regulated under 21 CFR 888.1100, Arthroscope and 21 CFR 876.1500, endoscope.

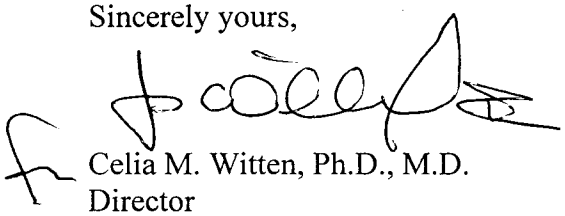
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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,



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): 982133

Device Name: Olympus Endoscopic System for Lumbar Hernia Discectomy

Indications For Use:

Olympus Endoscopic System for Lumbar Hernia Discectomy and its ancillary equipment are intended for visualizing lumbar disc, lumbar herniated disc material and lumbar paravertebral tissue, and aiding in search and removal of vertebral bone and nucleus material.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982133

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over-The-Counter Use ____

Optional Format (1-2-96)

OCT 22 1998

K982133

510(k) Summary
for
Olympus Endoscopic System for Lumbar Hernia Discectomy

1. SPONSOR/APPLICANT NAME, ADDRESS

Olympus Optical Co. Ltd.
Endoscope Division
2951 Ishikawa-Cho
Hachioji, Tokyo 192-8507
Japan

Contact Person: Shigeyoshi Terawaki
Telephone: 0426-42-5101
Facsimile: 0426-42-9979

DATE OF SUMMARY PREPARATION: June 16, 1998

2.

TRADE/PROPRIETARY NAME:	Endoscopic System for Lumbar Hernia Discectomy and its Ancillary Equipment
COMMON/USUAL NAME:	Endoscopic System for Lumbar Hernia Discectomy
CLASSIFICATION NAME:	Arthroscope and Accessories

3. IDENTIFICATION OF THE PREDICATE OR LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCE IS BEING CLAIMED:

Sofamor Danek's MED MicroEndoscopic Discectomy System, Sofamor Danek's INCL Endoscopic System (K955471), Rigid Arthroscope (K950501), and MICRO-END0 Instruments (K950130).

4. DEVICE DESCRIPTION

The Olympus Endoscopic System for Lumbar Hernia Discectomy and Accessories consist of the following components:

- Initial Placement Instruments

Instrument	Function
Guide Needle	Guide to target site
Dilators	Dilation of tissues
Mandolin	Guide of Flexible Sheath, and Dissection of tissue on lamina
Flexible Sheath	Delivery of Endoscope
Pusher	Delivery of Flexible Sheath
Side Sheath	Delivery of Endoscope

- Olympus XELSPAS Series Manual Surgical Hand Instruments
- Telescope - to view operative site
- Light Guide Adaptor - an adaptor to be used with commercially available light systems to provide illumination
- Surgical Holder Adaptor - an adaptor to be used to attach the endoscope to Olympus surgical holder device (510(k) K960068)

5. INTENDED USE

The Olympus Endoscopic System for Lumbar Hernia Discectomy is intended for visualizing lumbar disc, lumbar herniated disc material, and lumbar paravertebral tissue and for aiding in search and removal of vertebral bone and nucleus material.

6. STATEMENT OF HOW TECHNOLOGICAL CHARACTERISTICS COMPARE TO PREDICATE

The Olympus Endoscopic System for Lumbar Hernia Discectomy is substantially equivalent to Sofamor Danek's MED MicroEndoscopic Discectomy System in technological characteristics. Both include an endoscope (arthroscope) for visualizing lumbar discs, lumbar herniated disc material, and lumbar paravertebral tissue. The proposed Olympus Endoscope is also substantially equivalent to the Olympus Endoscope described in 510(k) K951354, in optical characteristics and

design. Both systems offer several surgical instruments for aiding in search and removal of vertebral bone and nucleus material. The materials of manufacture of the Olympus system are all standard material used in medical products. Additionally, the materials in the proposed Olympus Endoscopic System for Lumbar Hernia Discectomy are identical to those cleared in legally marketed Olympus devices.

Additionally, the components of the Olympus Endoscopic System for Lumbar Hernia Discectomy are substantially equivalent in design and dimensions to other Olympus devices.