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K991672
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510(k) SUMMARY
OLYMPUS NA-10J-KB Aspiration Needle

A. Submitter's Name, Address, Phone and Fax Numbers

1. Manufacturer of the subject devices

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 2-3-1 Shinjyuku Monolis Nishi-Shinjuku, Shinjyuku-ku Tokyo, Tokyo 163-0914 Japan
Registration No.:	8010047
Address, Phone and Fax Numbers: of R&D Department, Endoscope Division	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507 Japan TEL 0426-42-5101 FAX 0426-46-2786

B. Name of Contact Person

Name: Address, Phone and Fax Numbers:	Ms. Laura Storms-Tyler Olympus America Inc. Two Corporate Center Drive Melville, New York 11747-3157 TEL: (516) 844-5688 FAX: (516) 844-5416

C. Device Name, Common Name, Classification Name and Predicate Devices

Trade Name:	Olympus NA-10J-KB Aspiration Needle
Common Name:	Aspiration Needle
Classification:	Gastroenterology-urology biopsy instrument 21 CFR 876.1075 Endoscope and accessories 21 CFR 876.1500
Predicate Device:	Olympus NA-10J-1 Aspiration Needle K973128

D. Description of the Device(s)

This instrument has been designed to be used with the ultrasonic endoscope for ultrasonically guided fine needle aspiration(FNA) of submucosal and extramural lesions of the gastrointestinal tract(i.e. pancreatic masses, mediastinal masses peri-rectal masses and lymph nodes).
The NA-10J-KB consists of a handle section and a sheath section. This instrument is designed to be used with the needle section, MAJ-363.
The handle section is connected to the endoscope channel opening.
The handle section facilitates to advance the sheath section and the needle section manually. And the handle section projects the needle section rapidly by its spring mechanism. This spring mechanism is equipped to facilitate puncturing of indurated lesions. The projection length by the spring mechanism is adjustable.
The setting for projection length by spring-loaded needle is determined by observing the ultrasonic image.

E. Intended Use of the Device(s)

This instrument has been designed to be used with the ultrasonic endoscope for ultrasonically guided fine needle aspiration (FNA) of submucosal and extramural lesions of the gastrointestinal tract (i.e. pancreatic masses, mediastinal masses, peri-rectal masses and lymph nodes).

F. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate device, the Olympus NA-10J-KB Aspiration Needle does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 1999

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

Re: K991672
Olympus NA-10J-KB Aspiration Needle
Dated: August 10, 1999
Received: November 1, 1999
Regulatory Class: II
21 CFR §876.1075/Procode: 78 FCG

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 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). 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 requirements, 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991672

Device Name: Olympus NA-10J-KB Aspiration Needle

Indications for Use:

This instrument has been designed to be used with the ultrasonic endoscope for ultrasonically guided fine needle aspiration (FNA) of submucosal and extramural lesions of the gastrointestinal tract (i.e. pancreatic masses, mediastinal masses, peri-rectal masses and lymph nodes).

(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)

David G. Hegarty

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991672/S001

(Optional Format 1-2-96)