

NOV 18 1997

K973128

P1091

**510 (k) SUMMARY  
OLYMPUS NA-10J-1 ASPIRATION NEEDLE**

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.

**Device Name:** Olympus NA-10J-1 Aspiration Needle

**Common/Usual Name:** Biopsy Instruments

**Classification Name:** 21 CFR 876.1075  
Gastroenterology-Urology Biopsy Instruments

**Predicate Devices:** Olympus NA-1C Aspiration Needle (K904667)

**Prepared & Submitted By:** Linda L. Favata  
**(Contact Person)** Olympus America Inc.  
Endoscope Division  
Two Corporate Center Drive  
Melville, New York 11747-3157  
(516) 844-5477

**Summary Preparation  
Date:** 07/25/97

**Statement of Intended Use:**

The Olympus NA-10J-1 Aspiration Needle is specifically designed to be used with the Olympus GF-UM30P ultrasound gastroscope for ultrasonically guided fine needle aspiration (FNA) of submucosal and extramural lesions of the gastrointestinal tract (i.e., pancreatic masses, mediastinal masses, peri-pancreatic masses, and lymph nodes).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 18 1997

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

Re: K973128  
Olympus NA-10J-1 Aspiration Needle  
Dated: August 19, 1997  
Received: August 21, 1997  
Regulatory Class: II  
21 CFR §876.1075/Product Code: 78 FOG

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) 594-4613. 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/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use Statement**

**510(k) Number (if known):**

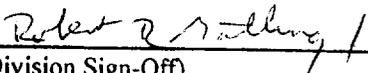
Not assigned yet

**Device Name:**

Olympus NA-10J-1 Aspiration Needle

**Indications for Use:**

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\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number 1K973128

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(per 21CFR 801.109)

OR

Over-the Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)