K050503
1 of 2

MAY 12 2005

# SMDA 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR, Part 807, Subpart E, Section 807.92.

## A. GENERAL INFORMATION

### 1. Applicant

Name & Address: Aomori Olympus Co., Ltd.
2-248-1 Okkonoki Kuroishi-shi,
Aomori-ken, Japan 036-0357

Registration Number: 9614641

### 2. Initial Importer

Name & Address: Olympus America Inc.
Two Corporate Center Drive,
Melville, NY 11747-9058

Registration Number: 2429304

### 3. Submission Correspondence

Name, Address, Tel & Fax: Laura Storms-Tyler
Director, Regulatory Affairs and Quality Assurance
Olympus America Inc.
Two Corporate Center Drive,
Melville, NY 11747-9058
TEL 631-844-5688
FAX 631-844-5554

Registration Number: 2429304

## B. DEVICE IDENTIFICATION

### 1. Common/Usual Name
Aspiration Needle

### 2. Device Name
Single Use Aspiration Needle NA-201SX-4022

### 3. Class, Classification Number, and Classification Name
Class II, 21CFR 876.1075, Set, Biopsy needle, Gastro-urology

K050503
2 of 2

## C. PREDICATE DEVICES

| Device Name | 510(k) # | Manufacturer | Class | Product Code |
|---|---|---|---|---|
| EVIS EXERA Ultrasonic Bronchofibervideoscope Olympus BF Type UC160F-OL8, OLYMPUS EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center | #K042140 | Olympus Corporation | II | KOG |
| VACLOK Syringe | #K994253 | Merit Medical System Inc. | II | FMF |
| STOPCOCK(One-port manifold) | #K934123 | Merit Medical System Inc. | II | DTL |
| Disposable Aspiration Needle NA-200H | #K023272 | Olympus Corporation | II | FCG |

## D. DESCRIPTION OF THE DEVICE

The NA-201SX-4022 Single Use Aspiration Needle consists of a handle section, needle section, and sheath section. The handle section is connected to the endoscopes instrument channel port via the single use adapter biopsy valve (MAJ-1414). The handle section facilitates the advancement of the needle section during puncture of the targeted site. The syringe (VACLOK Syringe and Stopcock) is attached to the aspiration port on the handle section of the NA-201SX-4022. The syringe is used to aspirate the specimen that was punctured with the needle. The syringe has a lock function which can lock the piston (plunger) is pulled. When the stopcock is closed and the piston (plunger) keeps it evacuated. For aspiration, the syringe should be connected with the needle and the stopcock should be opened just before aspiration. The lock function eliminates the need for the operator to keep pulling the piston during the procedure thus improving usability. The position to lock the piston (plunger) is selected from 4 levels. Accordingly, the operator can select the specimen size required.

## E. INTENDED USE OF THE DEVICE

This instrument has been designed to be used with ultrasonic endoscopes for ultrasonically guided fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree and the gastrointestinal tract.

## F. REASON FOR NOT REQUIRING CLINICAL DATA

When compared to the predicate device, the Single Use Aspiration Needle NA-201SX-4022, MAJ-1414 and Syringe does not incorporate any significant change that impacts safety and efficacy in comparison to the predicate device. Therefore, clinical data is not necessary to establish the subject device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2005

Olympus Medical Systems Corporation
C/O Ms. Larua Storms-Tyler
Director, Regulatory Affairs and Quality Assurance
Olympus America, Incorporated
Two Corporate Center Drive, USA
Melville, New York 11747-9058

Re: K050503
Trade/Device Name: Single Use Aspiration Needle NA-201SX-4022
Regulation Number: 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: II
Product Code: FCG
Dated: February 18, 2005
Received: February 28, 2005

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.

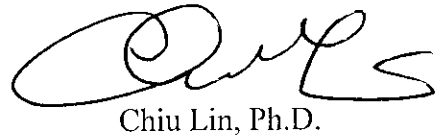
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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 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/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050503

1 of 1

# Indications for Use

510(k) Number(if known):

Device Name:

Single Use Aspiration Needle NA-201SX-4022

Indications for Use:

This instrument has been designed to be used with ultrasonic endoscopes for ultrasonically guided fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree and the gastrointestinal tract.

Do not use this instrument for any purpose other than its intended use.

Prescription Use ✓ OR Over-The-Counter Use _____

(21 CFR 601 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050503