K033222

AUG - 2 2004

510(k) Summary
Olympus Sterilization Trays

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

A. Submitter's Name, Address, Phone, Contact Person and Summary Date

Manufacturer of subject device:	Olympus Winter & Ibe Kuehnstr. 61 D-22045 Hamburg Germany
Registration number:	8010313
Contact Person:	Tina Steffanie-Oak Olympus America Inc. Two Corporate Center Drive Melville NY 11747-3157 Registration Number: 2429304 Telephone: (631) 844-5477

B. Device Name

Device Name:	Olympus sterilization trays
Common/Usual Name:	Sterilization container
Classification Name:	Sterilization container
Classification:	21 CFR 882.1480 Class II

C. Predicate Devices:

PolyVac Delivery Systems (K012105)

D. Device Description

The Sterilization trays, which are the subject of this premarket notification, are as follows:

Item no.	Outer dimensions WxHxD[mm]	Detailed product description
A5938*	595 x 61 x 295	Instrument tray, with lid, for video telescope
A5951*	478 x 41 x 224	Insert tray, for 2.7 and 4.0 mm TruView arthroscopes
A5952*	478 x 41 x 224	Insert tray, for Diver-Line hand instruments
A5961*	665 x 52 x 204	Insert tray, for ureteroscopes, with lid
A5975*	532 x 63 x 128	Instrument tray, small, with lid
A5976*	478 68 224	Insert tray, for urology
A5977*	478 x 68 x 224	Insert tray, for 4 TroQ trocars
A5984*	Set: A5994 and WA05974	Instrument tray, for camera head and adapter
A5992*	478 x 54 x 224	Instrument tray, for A3336A, A2027A and A5226A
A5994*	478 x 68 x 224	Insert tray, for camera head and adapter
A05951A*	478 x 41 x 224	Insert tray, for TrueView II and mini TrueView telescopes
A05952A*	665 x 65 x 204	Instrument tray, for SonoSurg instruments, with lid
A05961A*	405 x 95 x 200	Instrument tray, for compact cystoscope and compact hysteroscope, with lid
WA05970A	537 x 139 x 268	Instrument tray, with lid and silicone mat
WA05971A	482 x 60 x 224	Insert tray, for the upper part of WA05970A, with silicone mat
WA05972A	480 x 47 x 224	Insert tray, for 5 HiQ shafts and jaw inserts
WA05973A	460 x 39 x 207	Insert tray, for the bottom of WA05970A, with silicone mat
WA05974A	488 x 31 x 235	Lid, for insert trays
WA05980A	438 x 176	Spare mat, nubbly, silicone, for WA05970A and WA05971A
WA05981A	400 x 175	Spare mat, nubbly, silicone, for WA05973A
WA05990A	446 x 88 x 49	Instrument tray, for two telescopes, with lid
WA05994A*	478 x 68 x 224	Insert tray, for camera head and adapter
WA05995A*	478 x 68 x 224	Insert tray, pediatric urology
WA59380A*	595 x 61 x 295	Instrument tray, for video telescope

The Olympus sterilization trays consist of perforated bottoms with or without perforated lids. The material of the bottom is thermoplastic, the material of the lid is thermoplastic with handles and locking tabs made from medical grade stainless steel. The silicone mats for fixture of the instruments are perforated for aeration.
The stripes are designed for minimal contact area with instruments and secure fixing.

Olympus sterilization trays will be sold non-sterile and can be reused after proper cleaning and sterilization.

E. Intended Use of Device

The Olympus sterilization trays are intended to be used to enclose Olympus medical devices including hand instruments, trocars, camera heads, adapter, and endoscopes to be sterilized by a health care provider. It is intended to allow steam sterilization of the enclosed medical device.

The qualification for sterilizing endoscopic instruments were validated with a process challenge device (PCD) by a GLP approved laboratory. The PCD has a diameter of 2 mm and a length of 1500 mm.

The Olympus sterilization trays are to be sterilized in the following cycle:

Prevacuum Steam: 132°C - 134°C - 5 minutes minimum

Drying Time: 10 – 20 minutes as needed.

Comparison to Predicate Devices

	Subject Olympus Sterilization Trays	Predicate PolyVac's Delivery Systems
ELEMENT		
Intended Use: to enclose medical devices during steam sterilization.	Yes	Yes
Intended to be reused	Yes	Yes
Material Composition	Thermoplastic RADEL®	Thermoplastic RADEL®
Consist of base with lid, lid can be fastened to the base by a locking tab	Yes	Yes
Usable with silicone mats or special silicone holders	Yes	Yes
PERFORMANCE		
Sterilant Pentration for Steam with Prevacuum validated	Yes	Yes
Microbial Barrier Properties	To be used with approved sterilization wrap	To be used with approved sterilization wrap
Material Compatibility	Compatible to Steam Sterilization at 134°C	Compatible to Steam Sterilization at 132°C
Toxicological Properties	Material biocompatible	Material biocompatible
Shelf Life	depends on wrapping material and storage conditions.	n.a.
Drying time	10 – 20 minutes	20 – 40 minutes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 2 2004

Olympus Winter & Ibe GmbH
C/O Ms. Tina Steffanie-Oak
Olympus America, Incorporated
Two Corporate Center Drive
Melville, New York 11747-3157

Re: K033222
Trade/Device Name: Olympus Sterilization Trays
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: May 20, 2004
Received: May 21, 2004

Dear Ms. Steffanie-Oak:

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.

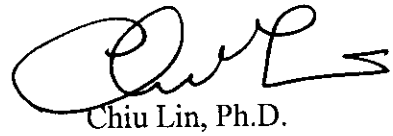
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4618. 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/dsma/dsmamain.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

510(k) Number (if known): K033222

Device Name: Olympus Sterilization Trays

Indications for Use:

The Olympus sterilization trays are intended to be used to enclose Olympus medical devices including hand instruments, trocars, camera heads, adapter, and endoscopes to be sterilized by a health care provider. It is intended to allow steam sterilization of the enclosed medical device.

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Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 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: K033222