

JUN 25 2002

K014166

## 510(k) SUMMARY

### HIGH FLOW INSUFFLATION UNIT UHI-3

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

#### A. Submitter's Name, Address, Phone and Fax Number

##### 1. Manufacturer of the subject device

Name & Address of Manufacturer;	Olympus Optical Co., Ltd. 2-3-1 Shinjuku Monolis Nishi-shinjuku Shinjuku-ku, Tokyo, 163-0914 Japan
Registration No :	8010047
Address, Phone and Fax Number of R&D Department Endoscope Division	2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan TEL 81-426-42-5177 FAX 81-426-46-5613

##### 2. Name of Contact Person

Name :	Ms.Laura Storms-Tyler Director, Regulatory Affairs Olympus America Inc. Two Corporate Center Drive Melville, NY 11747-3157
Address, Phone and Fax :	TEL (631)844-5688 FAX (631) 844-5416

#### B. Device Name, Common Name

1. Device Name :	UHI-3 HIGH FLOW INSUFFLATION UNIT
2. Common/Usual Name :	HIGH FLOW INSUFFLATION UNIT
3. Classification Name :	Laparoscopic Insufflator 21CFR884.1730, Class II

### C. Predicate Devices:

Model	Device Description & 510(k)#/ Date Cleared	Manufacturer
OLYMPUS High Flow Insufflation Unit UHI	#K953162 12/19/1995	Olympus Optical Co., Ltd.
NORTECH Omniflator 7640 Model 7-640-00	#K983326 02/05/1999	Northgate Technologies, Inc.

### D. Description of the Device

This instrument has been designed for insufflation of the abdominal cavity, and automatic suction and smoke evacuation. This instrument uses CO<sub>2</sub> gas for distension, and it may be used for diagnostic and/or operative laparoscopy.

This instrument is constituted of High Flow Insufflation Unit UHI-3, Suction Tube and Insufflation Tube, and they are used with Recommended Accessories (Optional) and Ancillary Equipment.

And auto smoke evacuating function of UHI-3 works by combining with the Olympus high frequency unit (UES-20 / 30) or ultrasonic surgery unit (SonoSurg-G / G2)

#### 1. High Flow Insufflation Unit UHI-3

The High Flow Insufflation Unit UHI-3 has been designed for insufflating CO<sub>2</sub> gas into abdominal cavity during a laparoscopic procedure. This provides a clear view and space for laparoscopic instrumentation to be used. The UHI-3 has suction capability for the purpose of evacuating smoke caused by HF instruments. The suction ability can also be used as a secondary system to evacuate the abdominal cavity in an over-pressure condition. The suction is controlled with an external suction unit through the pinch valve.

#### 2. Suction Tube

The suction tube is designed to be used with the Olympus UHI-3 High Flow Insufflation Unit, and a trocar to assist in maintaining a clear field of view by evacuating smoke from the operating sight during laparoscopic surgery.

#### 3. Insufflation Tube

The Insufflation tube is designed to be connected to the Olympus UHI-3 High Flow Insufflation Unit, to supply CO<sub>2</sub> gas to the abdominal cavity.

### E. Intended Use of the device

This instrument has been designed for insufflation of the abdominal cavity, and automatic suction and smoke evacuation. This instrument uses CO<sub>2</sub> gas for distension, and it may be used for diagnostic and/or operative laparoscopy.

### F. Reason for not requiring clinical data

The subject HIGH FLOW INSUFFLATION UNIT UHI -3 is similar to the OLYMPUS High Flow Insufflation Unit (UHI) cleared in the previous 510(k) (#953162).

Though the maximum flow rate of the previous device, High Flow Insufflation Unit UHI is 12 l/min, less than 20 l/min, which is the maximum flow rate which FDA has currently cleared for marketing

laparoscopic Insufflators, the maximum flow rate of this subject device is 35 l/min over the current FDA's cleared level.

However the maximum flow rate of OMNIFLATOR 7640 MODEL 7-640-00 cleared in the previous 510(k) (#983326) is 40 l/min.

And when compared to the predicated devices listed above, the Olympus High Flow Insufflation Unit UHI-3 does not incorporate any significant change in intended use, method of operation, material, or design that could affect safety and effectiveness. Then it is judged that clinical data is not needed.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUN 25 2002**

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

Re: K014166  
Trade/Device Name: Olympus UHI-3 High  
Flow Insufflation Unit  
Regulation Number: 21 CFR 884.1730  
Regulation Name: Laparoscopic insufflator  
Regulatory Class: II  
Product Code: 85 HIF  
Dated: April 22, 2002  
Received: April 29, 2002

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 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.

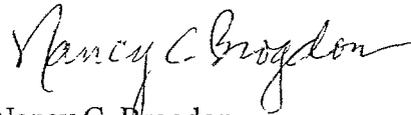
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## INDICATION FOR USE STATEMENT

510(k) Number (if known):

Device Name: HIGH FLOW INSUFFLATION UNIT UHI-3

**Indications for Use:**

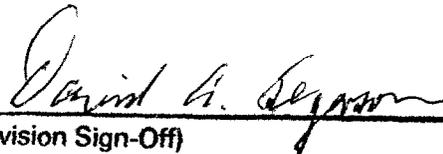
This instrument has been designed for insufflation of the abdominal cavity, and automatic suction and smoke evacuation. This instrument uses CO<sub>2</sub> gas for distension, and it may be used for diagnostic and/or operative laparoscopy.

Concurrence of CDRH, Office of Device Evaluation ODE

Prescription Use

Prescription Use X OR Over-The-Counter Use  
(Per 21 CFR 801.109)

(Optional Format 1-2-96)



(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

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