K081094

JUN 20 2008

Section 1 - Administrative Information

1.1 - 510(k) Summary of Safety & Effectiveness

1.1.1 Classification

Class II

1.1.2 Owner/Contact

Steve C. Hesler
Director, Quality Assurance and Regulatory Affairs
Olympic Medical, Division of Natus
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Seattle, WA 98108
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Fax (206) 762-5104
Prepared: 6/20/2008

1.1.3 Device Name

Trade Name:	Olympic Pasteurmatic 3000 Olympic Pasteurmatic 3500
Common Name:	Medical washer-disinfector
Classification Name:	Device, Pasteurization, Hot Water (21 CFR 880.6992, Product Code MEC)
Regulatory Class:	II
ERN:	3018859

1.1.4 Predicate Device

Olympic Pasteurmatic System (K953645).

1.1.5 Device Description

The Olympic Pasteurmatic 3000 and Olympic Pasteurmatic 3500 are used for the cleaning and high-level disinfection of reusable and disposable breathing circuit parts used in Respiratory Therapy and Anesthesia. Pasteurization kills pathogenic vegetative bacteria and viruses by immersion in water at 160° – 170° F for 30 minutes. Full immersion pasteurization has been identified by the Centers for Disease Control as suitable for high-level disinfection of all parts not used subcutaneously.

The Olympic Pasteurmatic 3000 and Olympic Pasteurmatic 3500 are identical systems with the exception of the heater capacity. The Pasteurmatic 3000 has three 3,000 watt heaters for a system capacity of 9,000 watts. The Pasteurmatic 3500 has three 5,000 watt heaters for a system capacity of 15,000

watts to allow more rapid heating of the water during the pasteurization cycle when used as a combined washer-pasteurizer.

Both systems rotate stainless steel baskets of tubes and parts vertically in a stainless steel tank during both washing and pasteurizing. This forces water through the full length of the tubes and drives out all the air bubbles.

1.1.6 Intended Use

The Olympic Pasteurmatic 3000 and Olympic Pasteurmatic 3500 are intended for cleaning and high-level disinfection of respiratory therapy and anesthesia equipment by killing vegetative bacteria and viruses, in a hot water bath at ~160° – ~170° F for 30 minutes.

1.1.7 Comparison to Predicate Device

The Pasteurmatic 3000 and Pasteurmatic 3500 perform all the functions of the Olympic Pasteurmatic system using a digital user interface in place of the electromechanical timer and controls used in the predicate device. Additional convenience features have been added to the Pasteurmatic 3000 and Pasteurmatic 3500.

1.1.8 Summary of Comparison Tests

Tests were performed to demonstrate that the performance of the Pasteurmatic 3000 and Pasteurmatic 3500 meet or exceed that of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 2008

Mr. Steve Hesler
Director, Quality Assurance and Regulatory Affairs
Olympic Medical Corporation
Division of Natus
5900 First Avenue, South
Seattle, Washington 98108

Re: K081094
Trade/Device Name: Olympic Pasteurmatic, Models 3000 and 3500
Regulation Number: 880.6992
Regulation Name: Medical Washer-Disinfector
Regulatory Class: II
Product Code: MEC
Dated: May 22, 2008
Received: May 23, 2008

Dear Mr. Hesler:

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.

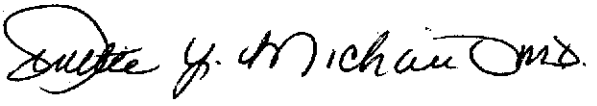
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number: K081094

Device Name: Olympic Pasteurmatic 3000 and Pasteurmatic 3500

Indications For Use:

The Olympic Pasteurmatic 3000 and Olympic Pasteurmatic 3500 are intended for cleaning and high-level disinfection of respiratory therapy and anesthesia equipment in a hot water bath at 160° – 170° F for 30 minutes.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X____ (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)

Sheila F. Murphy MD

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

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