

K 972193

SEP - 5 1997

SAFETY AND EFFECTIVENESS SUMMARY

*This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Olympic Medical
5900 First Ave. S.
Seattle, WA 98108
206-767-3500

Contact Person: Joseph Stefanile

Common or usual name of device
Trade or proprietary name
Classification name (if known)
Predicate device(s) to which substantial
equivalence is being claimed

Mini-Pasteurizer
Olympic Mini-Pasteurmatic™
80 LDS
Olympic Pasteurmatic

Device Description

1. Brief explanation of how the device functions.

The Olympic Mini-Pasteurmatic is a small, compact machine, which makes use of pasteurization to achieve high-level disinfection of respiratory therapy and anesthesia breathing circuit parts.

After hand washing, the parts are placed in the drum shaped "basket." The basket is submerged in hot water and rotated vertically. This vertical rotation flushes water through tubes and other hollow parts, allowing air to escape and improving water contact with all surfaces of the parts.

The Mini-Pasteurmatic is filled with water, which is heated to pasteurizing temperature by internal heaters.

2. Basic scientific concepts that form the basis for the device.

Pasteurization - Hot water disinfection (pasteurization) is a high-level, nontoxic disinfection process that is particularly useful for items such as respiratory therapy and anesthesia breathing circuits.

3. Significant physical and performance characteristics of the device. (Ex. device design and physical properties)

Model	Olympic Mini-Pasteurmatic
Controls	<ul style="list-style-type: none">• Power Switch with separate indicator light• Cycle Start• Paper Advance
Signals	<ul style="list-style-type: none">• Power On• Cycle On• Cycle Time Display• Cycle Temperature Display including °C or °F• Low Water
Interlock	Raising lid stops cycle
Electrical Approval	CSA, Class 8711-02, Electromedical Appliances
FDA Reference	Number not yet assigned
Size	26"W x 21-3/4"D x 28"H (lid raised)
Electrical	115 VAC, 60 Hz, less than 15 Amps
Accessories	Mesh Parts Bags
Warranty	Two Years; Five Year available
Loading Volume	0.46 cubic feet
Cycle Time	30 minutes
Water Temp Calibration Set Point	Not User Adjustable Factory set to 166°F

4. Intended Use of the device

Machine for pasteurizing (high-level disinfection) respiratory therapy and anesthesia parts, in a health care setting by health care workers.

5. Does the indication statement (4) differ from those of the predicate device?

Check one: Differs (complete section 6)
 Does not differ (skip to section 7)

6. Explanation of what the differences are not critical to the intended use of the device and why the differences do not affect the safety or effectiveness of the device.

N/A

7. The technological characteristics of the device compared to the predicate product.

See Comparison Chart on following page.

8. A brief description of tests and their results.

Tests were performed to verify the following:

- Water temperature remains within specified tolerances
- Overtemperature thermostat performance
- Cold water start time

9. Conclusions drawn from these tests that demonstrate the device is safe, effective, and performs as well or better than the legally marketed device.

The modified device and the predicate device are functionally identical for all parameters affecting safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Joseph P. Stefanile
Official Correspondent
Olympic Medical Corporation
5900 First Avenue South
Seattle, Washington 98108

SEP - 5 1997

Re: K972193
Trade Name: Olympic Mini-Pasteurmatic (58210)
Regulatory Class: Unclassified
Product Code: LDS
Dated: June 6, 1997
Received: June 10, 1997

Dear Mr. Stefanile:

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 (Pre-market 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

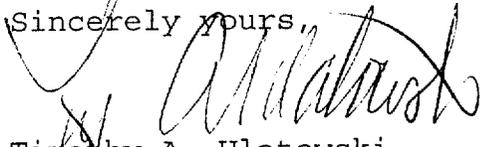
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4618. 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,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

