

K971117

AUG 22 1997

Date: _____
By: _____

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

Warming Cabinet
Olympic Warmette Model 30, 31, 40
80, Class II General Hospital
Olympic Warmette Model 10

Device Description

1. Brief explanation of how the device functions.

All Olympic Warmettes are essentially double walled, insulated cabinets with transparent doors.

The Warmettes normally remain on continuously. The temperature is user selectable.

The Model 10 uses a resistance element heater encapsuled in a high temperature silicone or kapton material bonded to the underside of the interior. Due to the small size, forced air circulation is not needed.

The Models 30, 31 and 40 make use of a fan to force recirculating air past resistance heating elements (located above the main chamber) and then into the main chamber. Air is returned to the heaters via an air duct built into the left wall. The Models 31 and 40 differ from the Model 30 in two respects:

- The selectable maximum temperature is higher.
- The delivery duct/plenum inside the right wall is more efficient, allowing the Models 31 and 40 to operate at the higher temperatures.

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

- Resistance heating elements
- Thermostatic temperature controls
- Fluid flow (air speed, plenum back pressures, exit air velocity)

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

Temp Range	Model 30	80° - 135°F
	Models 31,40	90° - 145°F ¹
Dimensions		84¼"H x 26"W x 21"D
Internal Capacity		13.5 cu. ft.
Accuracy		± 10°F

¹ Preliminary specifications—will not exceed the range of the predicate device 75° - 150°F

4. Intended Use of the device

The Olympic Warmette is intended to be used for warming of blankets/linen or solutions.

The solutions must be for external use only. The Warmette is not intended to be used for solutions with low boiling points or solutions containing flammable solvents or vehicles.

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 why 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.

**COMPARISON CHART - DEVICE CHARACTERISTICS
COMPARED TO PREDICATE PRODUCTS**

Model	Predicate Device 10	30	31	40
Manufacturer	Olympic Medical	←	←	←
Electrical Power	120V, 60 Hz, 1.5 amps	120V, 60 Hz, 8.0 amps	120 V, 60 Hz, 14 amps	←
Heater Wattage	150 W	900 W	1500 W	1500 W
Power Cord	3 Conductor 18 AWG Hospital Grade Connector	←	←	←
Adjustable Temperature Range	75° - 150°F	80° - 135°F	90° - 145°F ¹	←
External Dimensions	16"H x 20"W x 15"D	84¼"H x 26"W x 21"D	←	←
Capacity, Cu. Ft.	1.2	13.5	←	←
Accuracy	± 10°F	←	←	←
Controls	• Power Switch • Set Temp Control	←	←	←
Indicators	• Power On • Heater On • Oven Set Temp	←	←	←
Design Standards	CSA/NRTL-C UL-544	←	←	←
Heater Type	Radiant Element (encapsulated)	Radiant Element (forced air system)	←	←

¹ Preliminary specification shown--will not exceed the range of the Predicate Device 75° - 150°F

8. A brief description of nonclinical tests and their results.

Extensive verification testing performed including:

1. Temperature tests of all interior and exterior surfaces.
 2. Temperature tests of blankets/linen and solutions placed inside the Warmette.
 3. Current leakage and dielectric withstand test.
 4. Ground impedance.
 5. Overtemperature thermostat safety test.
9. Conclusions drawn from nonclinical and clinical tests that demonstrate the device is safe, effective, and performs as well as or better than the legally marketed device.

The nonclinical testing verifies the device meets its specifications and technological characteristics (as described in chart, Question 7). The performance is equivalent to the predicate device, in all critical parameters (temperature, accuracy, etc.).



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Ms. Julie Freed
Senior Regulatory Affairs Specialist
Olympic Medical
5900 First Avenue South
Seattle, Washington 98108

APR - 1 2011

Re: K971117
Trade/Device Name: Warmette
Regulatory Class: Unclassified
Product Code: LHC
Dated: May 28, 1997
Received: May 30, 1997

Dear Ms. Freed:

This letter corrects our substantially equivalent letter of August 22, 1997.

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 (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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Anthony Watson'.

Anthony Watson, B.S., M.S., M.B.A.
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): K 97117

Device Name: OLYMPIC WARMETTE

Indications For Use:

FOR WARMING OF BLANKETS/LINEN OR SOLUTIONS
SOLUTIONS MUST BE FOR EXTERNAL USE ONLY.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rebecca C. ...
(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K 97117

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use