K073675

MAY - 8 2008

510(k) SUMMARY

DATE PREPARED

December 27, 2007

INTRODUCTION

According to the requirements of 21 CFR 807.92, the following provides sufficient detail to understand the basis for a determination of substantial equivalence.

CONTACT INFORMATION

Submitter:
Gaymar Industries, Inc.
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Orchard Park, NY 14127
716.662.8636
Contact Person: Greg Pepe

Application Correspondent:
Hodgson Russ LLP
140 Pearl Street, Suite 100
Buffalo, NY 14202
716.848.1554
Contact Person: Bethany Gilbert, Esq.

DEVICE NAME

Proprietary Name: T-Pump Localized Temperature Therapy Pump

Catalog Numbers: TP650, TP650C, TP700, TP700C

Common Name: Temperature Therapy Pump

Classification Name: Pack, Hot or Cold Pack, Water Circulating

PREDICATE DEVICE

Gaymar Industries, Inc. ("Gaymar") claims substantial equivalence to:
1. Gaymar Industries, Inc. T-Pump Temperature Therapy Pump (K760804)
2. Adroit Medical Systems, Inc. HTP-1500 Localized Heat Therapy Pump (K970197)

DEVICE DESCRIPTION

The T-Pump Localized Temperature Therapy Pump is a small electronically controlled water heater that supplies warm or cold water at controlled temperatures to a water circulating pad for the application of localized temperature therapy. The control unit is an electrical device that uses a heating element to increase the temperature of water to controlled temperature set points,

which the user selects from the digital display face. The temperature is controlled by a dual microprocessor control circuit and a thermostat to prevent overheating. To utilize the cold therapy option, the user adds ice water to the device, which will heat the water to a set point of 50 degrees Fahrenheit. The temperature range of the device ranges from 50 degrees Fahrenheit (for the cooling option) to 107 degrees Fahrenheit (the highest heating set point).

The T-Pump Localized Temperature Therapy Pump attaches to a connector hose that connects to the water-circulating pad; the temperature-controlled water flows from the pump to the pad. The pads are applied to the part of the body requiring temperature therapy, thereby providing the interface for the therapy.

The T-Pump Localized Temperature Therapy Pump measures, in inches, 11.5 x 8 x 8. The device weighs under 10 pounds with the unit filled with water; the water reservoir has a maximum capacity of 2750ml. The housing is composed of ABS Plastic and Polycarbonate.

The leakage current is 100 microamperes maximum, and the flow rate is 9 gph (34 lph) minimum, with the water circulating pad attached.

INTENDED USE

The T-Pump Localized Temperature Therapy Pump is intended for use in supplying warm or cold water at controlled temperatures via water circulating pad for the application of localized therapy in situations where a physician determines that temperature therapy is necessary or desirable.

Localized temperature therapy is of particular benefit in treating the following: orthopedic conditions such as acute injuries, chronic pain, lower back pain, muscle spasm and strains; skin trauma such as abscesses, boils, bruises, burns and contusions; other medical conditions such as chronic arthritis, neuritis, phlebitis, tendonitis and I.V. infiltration; and symptoms such as infection and localized pain.

SUBSTANTIAL EQUIVALENCE

Substantial equivalence is based on two predicate devices.

First, the T-Pump Localized Temperature Therapy Pump is substantially equivalent to the predicate T-Pump Temperature Therapy Pump. Both devices supply warm or cold water to a water-circulating pad for the application of localized heat or cold therapy. None of the device modifications pose risk to safety or effectiveness different from those posed by the predicate T-Pump Temperature Therapy Pump.

Second, the T-Pump Localized Temperature Therapy Pump is substantially equivalent to the predicate Adroit HTP 1500 Localized Heat Therapy Pump. Both devices use a digital interface and software to control the temperature of the circulating water. None of the device

modifications pose a risk to safety or effectiveness different from those posed by the predicate Adroit HTP 1500 Localized Heat Therapy Pump.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gaymar Industries, Inc.
% Hodgson Russ LLP
Ms. Bethany Gilbert
Associate Attorney
140 Pearl St., Suite 100
Buffalo, New York 14202

MAY - 8 2008

Re: K073675
Trade Name: T-Pump Localized Temperature Therapy Pump
Regulation Number: 21 CFR 890.5720
Regulation Name: Water Circulating Hot, Cold Pack
Regulatory Class: Class II
Product Code: ILO
Dated: March 21, 2008
Received: March 24, 2008

Dear Ms. Gilbert:

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.
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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: T-Pump Localized Temperature Therapy Pump

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

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

Neil R P Ogden for MRM

sion Sign-Off)
Concurrence of CDRH, Office of Device Evaluation (ODE)
sion of General, Restorative,
Neurological Devices

(k) Number K073675