

SEP 10 1997

510(k) Summary

a(1) Submitted by: Adroit Medical Systems, Inc.  
1146 Carding Machine Rd.  
Loudon, TN 37774  
423-458-8600

K970197

Contact Person: Richard L. Studer  
423-458-8600

Prepared on: January 17, 1997

a(2) Proprietary Name: HTP-1500 Localized Heat Therapy Pump  
Common Name: Heat Therapy Pump  
Classification Name: Water Circulating Hot or Cold Pack

a(3) Adroit Medical Systems, Inc. believes that the HTP-1500 Localized Heat Therapy Pump is substantially equivalent to the MICRO-TEMP models SMS-1000 and SMS-2000 Localized Heat Therapy Pumps which are currently distributed by Seabrook Medical Systems, Inc.

a(4) The HTP-1500 Localized Heat Therapy Pump is a small electronically controlled electric water heater containing a water reservoir, an electric resistance heater, a heat exchanger, an integral electric pump and associated tubing, hoses and fittings that allow it to be connected to a separate external pad. In use, the pump circulates water from the reservoir through the heat exchanger, associated tubing, hoses and fittings into and through the external pad. The operator, using a membrane switch keypad, selects the desired water temperature as observed and confirmed on a digital display. The electronic controller selectively turns on and off the electric resistance heater to heat the heat exchanger, thereby heating the water to the desired temperature. The actual water temperature is monitored and displayed on the digital display.

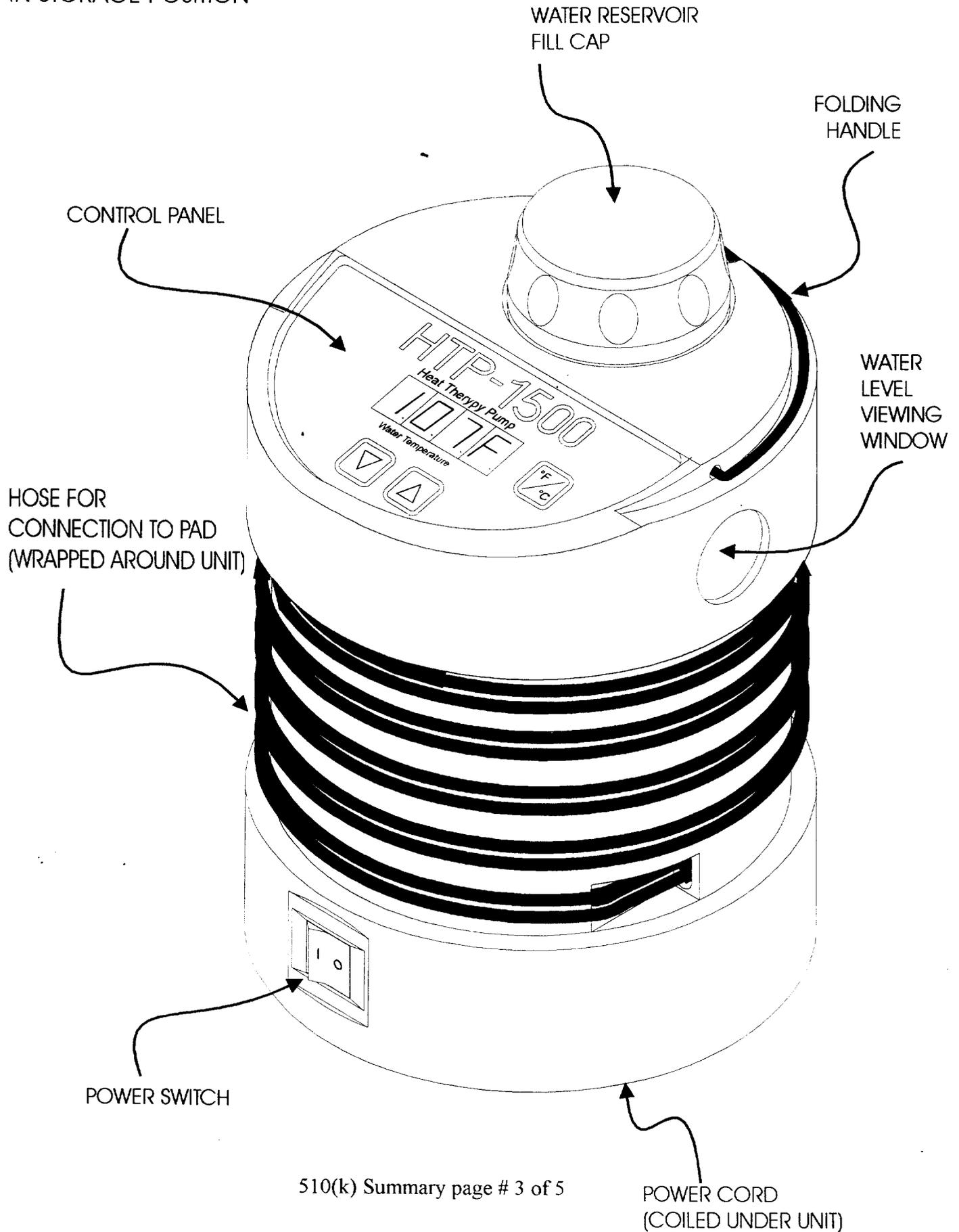
Included in this section is a three dimensional drawing of the HTP-1500 Localized Heat Therapy Pump showing the control panel, water reservoir fill cap, folding handle, water level viewing window, power switch, hose for connection to the pad, and the location of the power cord; and a schematic representation of an HTP-1500 connected to a pad.

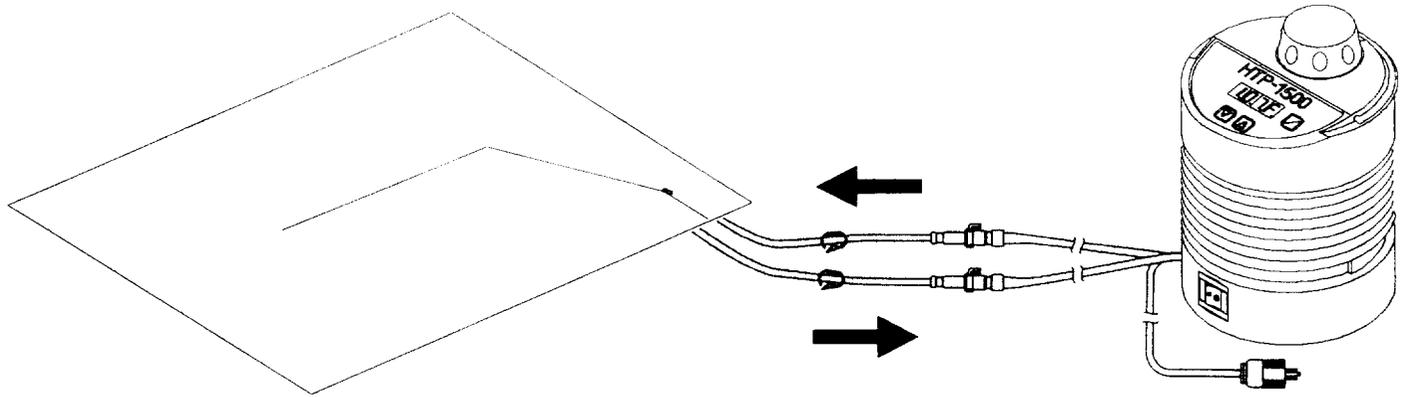
- a(5) The HTP-1500 Localized Heat Therapy Pump is intended for use in those situations where a physician determines that heat therapy is necessary or desirable.

Localized heat therapy is of particular benefit in, but not limited to, orthopedic conditions such as lower back pain, strains, acute injuries, chronic pain, muscle spasm, tendonitis, and arthritis. Heat therapy is also sometimes prescribed for skin trauma (bruises, contusions, abscesses, boils, burns) and other medical problems like infection, phlebitis, I. V. infiltration, and neuritis.

- a(6) The HTP-1500 Localized Heat Therapy Pump and the SMS-1000 and SMS-2000 MICRO-TEMP heat therapy pumps have substantially equivalent technological characteristics in that each use electrical resistance heaters to heat water, a solid state controller to control the temperature of the water, and an electric pump to circulate the water through a pad. This fact is further supported by the "SPECIFICATION COMPARISON" table included with this section.
- b This section is not required for this submission because substantial equivalence is based on intended use and device characteristics and specifications, and not on an assessment of performance data.

HTP-1500  
SHOWN WITH HOSE AND POWER CORD  
IN STORAGE POSITION





Pad

HTP-1500

HTP-1500 Hookup To Pad  
Note: Bi-directional Water Flow

## SPECIFICATION COMPARISON

	Adroit HTP-1500	Seabrook SMS-2000	Seabrook SMS-1000
<b>Physical</b>			
Size	7" Diameter, 8.5" High	8.5" Wide, 6.0625" Deep, 5.75" High	8.5" Wide, 6.0625" Deep, 5.75" High
Weight (empty)	7 Pounds	5.25 Pounds	4.7 Pounds
Connector Fitting Type	Quick-Connect	Quick-Connect	Quick-Connect
Housing Material	Polypropylene	G.E. Noryl Plastic	G.E. Noryl Plastic
Housing Color	Off White	Off White	Off White
<b>Electrical System</b>			
Voltage	115 Volt, 60 Hz.	115 Volt, 60 Hz.	115 Volt, 60 Hz.
Current	2.2 Amp.	1.75 Amp.	1.75 Amp.
Fuse	3 Amp., Type 3AG	3 Amp., Type 3AG	3 Amp., Type 3AG
Power Cord	3 Conductor, 18 AWG, 10 Feet Long, Hospital Grade Plug	3 Conductor, 18 AWG, 10 Feet Long, Hospital Grade Plug	3 Conductor, 18 AWG, 10 Feet Long, Hospital Grade Plug
Leakage Current	Less Than 50 Microamp	Less Than 50 Microamp	Less Than 50 Microamp
<b>Heating System</b>			
Temperature Range	75 °F to 107 °F	78 °F to 107 °F	86 °F to 107 °F
Heating Element	200 Watts	150 Watts	150 Watts
<b>Control System</b>			
Type	Digital, Solid State (Microprocessor based)	Digital, Solid State (Microprocessor based)	Analog, Solid State
Accuracy	+/- 1 °F (95 °F to 107 °F)	+/- 1 °F (Range ??)	+/- 1 °F (Range ??)
Self-Calibrating	No	Yes	Yes
Set Point Read Out	Digital Display	Digital Display	Analog Dial
Water Temperature Readout	Digital Display	Digital Display	None
Water Temperature Display Range	32 °F to 122 °F	31 °F to 121 °F	None
<b>Safety Range</b>			
Primary Limit Thermostat	Software Set at 109 °F	Hardware set at 113 °F +/- 3 °F	Hardware set at 113 °F +/- 3 °F
Secondary Limit Thermostat	Hardware set at 115 °F +/- 5 °F	Hardware set at 117 °F +/- 5 °F	Hardware set at 117 °F +/- 5 °F
Warning Lights	Flashing Display for Over Temperature	Light for Low Water and Over Temperature	Light for Low Water and Over Temperature
Audible Alarms	Over Temperature	Low Water and Over Temperature	None
<b>Circulating System</b>			
Reservoir Capacity	1.5 Liter (50.72)	0.89 Liter (30 Ounces)	0.89 Liter (30 Ounces)
Reservoir Fluid	Distilled Water	Distilled Water	Distilled Water
Fill Cap	Vented	Vented	Vented
Flow Rate Through Pad	10 to 14 GPH Average	10 to 14 GPH Average	10 to 14 GPH Average



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 10 1997

Mr. Richard L. Studer  
Adroit Medical Systems, Inc.  
P.O. Box 277  
Loudon, Tennessee 37774

Re: K970197  
HTP-1500 Localized Heat Therapy Pump  
Regulatory Class: II  
Product Code: ILO  
Dated: July 15, 1997  
Received: July 16, 1997

Dear Mr. Studer:

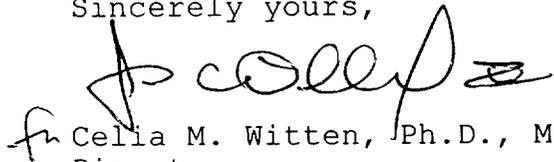
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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) 594-4659. 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,

  
Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): \_\_\_\_\_

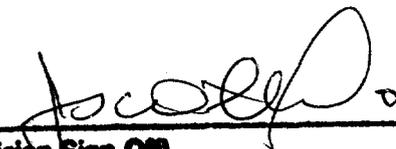
Device Name: HTP-1500 Localized Heat Therapy Pump

Indications For Use:

The HTP-1500 Localized Heat Therapy Pump is intended for use in those situations where a physician determines that heat therapy is necessary or desirable.

**CAUTION: Federal law restricts this device to sale by or on the order of a physician.**

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

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K970197

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The Counter Use \_\_\_\_\_

(Optional Format 1-2-96)