K040729

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SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTED BY: DYNATRONICS CORPORATION
7030 Park Centre Drive
Salt Lake City UT 84121
Phone: (800) 874-6251; (801) 568-7000; Fax: (801) 568-7711

1. DEVICE NAME (Trade/common, and classification): Solaris D890™ Therapy Probe.

Classification:	Class II
Regulation Nos.:	890.5500
Product Codes:	ILY

2. PREDICATE DEVICES:

   Solaris D880 Infrared Probe – Cleared under K031329

3. PERFORMANCE STANDARDS: The Solaris D890 conforms to the applicable requirements of 21 CFR sections 1010 (Performance Standards for Electronic Products: General) and 21 CFR sections 1040.10 and 1040.11 (Performance Standards for Light-Emitting Products).

4. DESCRIPTION: The Solaris D890™ is an infrared therapy accessory probe for use with Solaris Series combination devices. The base Solaris devices provide the operational power and software. The D890 probe contains only an on/off switch and requisite software to drive the infrared energy source.

5. INTENDED USE/INDICATIONS FOR USE: The Solaris D890 provides infrared therapy for the following allowed claims:

   Infrared therapy to provide topical heating for:
   - Temporary increase in local blood circulation
   - Temporary relief of minor muscle and joint aches, pains and stiffness
   - Relaxation of muscles
   - Muscle spasms
   - Minor pain and stiffness associated with arthritis

   The Intended Use/Indications For Use stated herein are identical to the cleared indications for the predicate device.

6. SUBSTANTIAL EQUIVALENCE (SE) RATIONALE: The Solaris D890 generates infrared therapy for treatment of selected medical conditions and shares the same or similar basic characteristics and the same intended use as the predicate device. Therefore, the proposed Solaris D890 is substantially equivalent to the Solaris D880 Infrared Probe, cleared under K031329

7. SAFETY AND EFFECTIVENESS: There are no substantive differences between the products defined in this 510(k) submission and the predicate devices. They are similar to the technologies that are currently used in other similar medical devices. They were developed and documented under Dynatronics' mature Quality Management System, under the Quality System Regulation, 21 CFR Part 820, under design/change control, and verified/validated to applicable standards/guidance documents. The Solaris D890 is safe and effective when used as indicated in specific applications under a clinician's supervision/therapy program.

Signed: Ronald J. Hatch Dated: 3/9/04

Ronald J. Hatch, VP Operations/RA
DYNATRONICS CORPORATION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2004

Mr. Ronald J. Hatch
Vice President Operations and Regulatory Affairs
Dynatronics Corporation
7030 Park Centre Drive
Salt Lake City, Utah 84121

Re: K040729
Trade/Device Name: Solaris™ D890™
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: March 10, 2004
Received: March 22, 2004

Dear Mr. Hatch:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
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): K040729

Device Name: Solaris™ D890™ Therapy Probe

Indications For Use:

Infrared therapy to provide topical heating for:

Temporary increase in blood circulation
Temporary relief of minor muscle and joint aches, pains and stiffness
Relaxation of muscles
Muscle spasms
Minor pain and stiffness associated with arthritis

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040729