K031329

OCT 2 2 2003

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): Dynatron® Solaris™ Series (model numbers 709, 708, 706, and 705); Therapeutic Ultrasound, Interferential Current Therapy, Electrical Muscle Stimulator, Electrotherapy, Non-Invasive Electrical Nerve Stimulator; Ultrasound and Muscle Stimulator (and Accessories), and Infrared therapy.

Classification:	Class II
Regulation Nos.:	882.5890, 890.5300, 890.5850, 890.5860 and 890.5500
Product Codes:	GZJ, IMI, IPF, IMG, LIH and ILY

2. PREDICATE DEVICES:
   Solaris 709 – Previously Dynatron 950, cleared under K950349 (Sep 13, 1995);
   Solaris 708 – Previously Dynatron 850, cleared under K941461 (Sep 01, 1995);
   Solaris 706 – Previously Dynatron 650, cleared under K950348 (Sep 13, 1995);
   Solaris 705 – Previously Dynatron 550, cleared under K941577 (Sep 01, 1995);
   Solaris D880 Infrared Probe – SE to MedX 1000 Series, cleared under K020017 (July 12, 2002)

3. PERFORMANCE STANDARDS: The Dynatron Solaris Series of devices conform to the applicable requirements of 21 CFR sections 1010 (Performance Standards for Electronic Products: General) and 1050 (Performance Standards for Sonic, Infrasonic, and Ultrasonic Radiation-Emitting Products).

4. DESCRIPTION: The Dynatron® Solaris™ Series (Model numbers 709, 708, 706, and 705) provide electrical stimulation, ultrasound, and/or electrical stimulation and ultrasound, as well as optional infrared therapy.

   Components:

   System console, containing software and control electronics with alpha-numeric displays

   Ultrasound transducer, infrared probe, and multi-probe for administering electrotherapy

   Accessories such as patient cables, electrodes, transducer gel and elastic straps.

5. INTENDED USE/INDICATIONS FOR USE: The Dynatron Solaris Series of products, including Solaris 709, 708, 706, and 705, provide electrical stimulation, ultrasound and/or combination electrical stimulation and ultrasound, as well as infrared therapy.

1) Electrical Muscle stimulation therapy for:
   - Relaxation of muscle spasms
   - Prevention or retardation of disuse atrophy
   - Increasing local blood circulation
   - Muscle re-education
   - Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
   - Maintaining or increasing range of motion

2) Transcutaneous electrical nerve stimulation and Interferential Current Therapy for:
   - Symptomatic relief of chronic intractable pain and/or management of post-traumatic or post-surgical pain.

3) Ultrasound therapy for:
   - Applying therapeutic deep heat within body tissues for the treatment of selected medical conditions such as:
     - Relief of pain
     - Muscle spasms
     - Joint contractures

4) 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 consistent with the cleared indications for the predicate devices.

6. SUBSTANTIAL EQUIVALENCE (SE) RATIONALE: The Dynatron Solaris 709, 708, 706, and 705, offer electrical stimulation, ultrasonic therapy and/or a combination of the two, and share the same or similar basic characteristics and the same general intended use in physical medicine, general and plastic surgery and neurology as the predicate devices. Therefore, the proposed Dynatron Solaris products are substantially equivalent to the Dynatron 950, 850, 650 and 550. The infrared therapy probe provides topical heating for treatment of selected medical conditions and shares the same or similar basic characteristics, features and intended use as the predicate and, therefore, is substantially equivalent to the MedX 1000 Series infrared probe (applicable 'K' numbers listed above).

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 is verified/validated to applicable standards/guidance documents. The Solaris family of electrical stimulation, ultrasound, and/or combination products, and accessories, are safe and effective, when used as indicated in specific applications under a clinician's supervision/therapy program.

Signed: Ronald J Hatch Dated: April 24, 2003

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

OCT 2 2 2003

Ronald J. Hatch
VP Operations/Regulatory Affairs
Dynatronics, Corp.
7030 Park centre Dr.
Salt Lake City, Utah 84121

Re: K031329

Trade/Device Name: Solaris Models 708 and 709
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic Diathermy
Regulatory Class: Class II
Product Code: IMI

Trade/Device Name: Solaris Models 705, 706, 708 and 709
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF

Trade/Device Name: Solaris Models 705, 706, 708 and 709
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: GZJ

Trade/Device Name: Solaris Models 705, 706, 708 and 709
Regulation Number: 21 CFR 882.5890
Regulation Name: Interferential Current Therapy
Regulatory Class: Class II
Product Code: LIH

Trade/Device Name: D880 Infrared Probe for use with Solaris Models 705, 706, 708 and 709
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Heat Lamp
Regulatory Class: Class II
Product Code: ILY

Dated: August 29, 2003
Received: September 4, 2003

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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 Statement

510(k) Number: K031329

Device Name: Dynatron® Solaris™ Series

Indications for Use:

Hi Volt, Russian, and Biphasic modes of stimulation are all forms of electrical muscle stimulation therapy available with the Solaris 709, 708, 706 & 705 and indicated for:

Relaxation of muscle spasms
Prevention or retardation of disuse atrophy
Increasing local blood circulation
Muscle re-education
Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
Maintaining or increasing range of motion

The Direct Current mode of stimulation is also a form of electrical muscle stimulation therapy available with the Solaris 709, 708, 706 & 705 and indicated for:

Relaxation of muscle spasms

IFC, Premodulated, Microcurrent and Diadynamic modes of stimulation are all forms of transcutaneous electrical nerve stimulation (TENS) or Interferential Current Therapy (IFC) available with the Solaris 709, 708, 706 & 705 and indicated for:

Symptomatic relief of chronic intractable pain and/or management of post traumatic or post-surgical pain

[continued]

for Mark N Milhoan

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

510(k) Number K031329

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Ultrasound therapy is available with the Solaris 709 & 708 and indicated for:

Applying therapeutic deep heat within body tissues for the treatment of selected medical conditions such as:

- Relief of pain
- Muscle spasms
- Joint contractures

Infrared therapy is available as an optional accessory (D880) probe with the Solaris 709, 708, 706 & 705 and indicated 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

for Mark N Melkerson

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

510(k) Number K031329