MAR 1 8 2009

510(k) # K083433

SUBMITTER:	Chattanooga Group 4717 Adams Road Hixson, TN 37343
ESTABLISHMENT REGISTRATION:	1022819
CONTACT:	Michael Treas, Director of Regulatory Affairs
DATE PREPARED:	November 17, 2008
PROPRIETARY NAME:	Intelect® SWD 100/ Senior Solutions®
CLASSIFICATION:	Class II
PRODUCT CODES:	IMJ
REGULATION NUMBER AND COMMON NAMES:	21 CFR 890.5290 Shortwave Diathermy
PANEL:	Physical Medicine

Indications for Use:

Indications for use in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as disorders of the musculoskeletal system, muscle spasm, joint stiffness, contractures, and chronic inflammatory or infective conditions such as tenosynovitis, bursitis, synovitis and chronic inflammatory pelvic diseases.

Generally accepted indications for use:

- Pain Relief
- Reduce Muscle Spasm
- Decrease Joint Stiffness
- Contractures
- Increase Blood Flow
- Chronic Inflammatory Conditions
- Bursitis
- Tenosynovitis
- Synovitis
- Chronic Inflammatory Pelvic Disease

Intended Use:

Intelect® SWD 100/ Senior Solutions® Shortwave Diathermy device for use in applying therapeutic deep heat for selected medical conditions by applying electromagnetic energy in the radio frequency band of 27.12 megahertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

Description:

The Intelect® SWD 100/ Senior Solutions® Shortwave Diathermy devices consists of a power supply that provides power to a radio frequency oscillator. This radio frequency oscillator provides stable, drift-free oscillations at the required frequency. The power amplifier generates the power required to drive the different types of electrodes. The output resonant tank tunes in the patient as part of the circuit and allows maximum power to be transferred to the patient.

The output intensity controls the percentage of maximum power transferred to the patient circuit. The tuning control adjusts the output circuit for maximum energy transfer from the radio frequency oscillator. The power output meter monitors only the current that is drawn from the power supply and not the energy being delivered to the patient.

The power output produces sufficient energy to raise the tissue temperature into a therapeutic range. The specific absorption rate (SAR) represents the rate of energy absorbed per unit area of tissue mass.

Patient sensation provides the basis for recommendations of continuous shortwave diathermy dosage and thus varies considerably with different patients. The following are recommended dosage guidelines:
Dose I (lowest): No sensation of heat
Dose II (low): Mild heating sensation
Dose III (medium): Moderate (pleasant) heating sensation
Dose IV (heavy): Vigorous heating that is tolerable below the pain threshold

Therapy may be delivered to the patient via either capacitance or induction techniques. The Intelect® SWD 100/ Senior Solutions® Shortwave Diathermy devices use the following accessories:
- Capacitive Electrodes
- Pair of 80mm round
- Pair of 120mm round
- Pair of 165mm round
- 180mm x 120mm flexible rubber electrodes
- 250mm x 145mm flexible rubber electrodes
- Inductive Electrodes
- Monode 14cm
- Diplode 18cm x 39cm

Each of these techniques can affect different biological tissues, therefore selection of the appropriate electrodes is essential for effective treatment.

Substantially Equivalent Predicate Devices

510(k) #	*Proprietary Name*	*Predicate Device Manufacture's*	*Device Classification Names*	*Regulation Numbers*	*Classification(s) and Product Codes*
K042554	Auto Therm 390	Mettler Electroinics, Corporation	Shortwave Diathermy	890.5290	Class II, IMJ
K030382	SeliTherm	Selicor, Inc.	Shortwave Diathermy	890.5290	Class II, IMJ
K022458	Auto Therm 395	Mettler Electronics, Corporation	Shortwave Diathermy	890.5290	Class II, IMJ
K973732	Megapulse II	PTI, Inc.	Shortwave Diathermy	890.5290	Class II, IMJ

Declarations of Conformity

The Intelect® SWD 100/ Senior Solutions® Shortwave Diathermy devices comply with the following FDA recognized Consensus Standards:

UL 60601-1: 2003, Standards for Medical Equipment Part 1: General Requirements for Safety, 1st Edition

IEC 60601-1-2: 2001, Medical Electrical Equipment Part 1 – 2: General requirements for Safety - Collateral Standard, Electromagnetic Compatibility – Requirements and Tests, 2nd Edition

IEC 60601-2-3: 1991, Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of Short-Wave Therapy Equipment; Amendment 1 – 1998, 2nd Edition (The United States FDA does not recognize IEC 60601-2-3)

IEC 60601-1-4: 2000, Medical Electrical Equipment – Part 1 – 4: General Requirements for Safety – Collateral Standard: Programmable Medical Electrical Systems Consolidated with Amendment 1, 1999

Truthful and Accurate Statement

A statement attesting to the truthfulness and accuracy of the information was included in the premarket submission.

Further Information

Contact:

Chattanooga Group
4717 Adams Road
Hixson, TN 37343
U.S.A.

Michael Treas, Director of Regulatory Affairs
Telephone: (423) 870-2281 ext. 7207
Fax: (423) 870-7404
Email: michael.treas@djoglobal.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2009

Chattanooga Group
% Mr. Michael Treas
Director of Regulatory Affairs
4717 Adams Road
Hixson, Tennessee 37343

Re: K083433
Trade/Device Name: Intelect® SWD 100/Senior Solutions® Shortwave Diathermy
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave diathermy
Regulatory Class: II
Product Code: IMJ
Dated: February 17, 2009
Received: February 18, 2009

Dear Mr. Treas:

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.

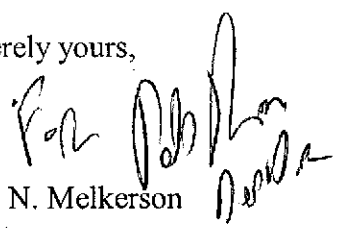
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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 Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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: _____

Device Name: Intelect® SWD 100/ Senior Solutions® Shortwave Diathermy

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Indications for use in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as disorders of the musculoskeletal system, muscle spasm, joint stiffness, contractures, and chronic inflammatory or infective conditions such as tenosynovitis, bursitis, synovitis and chronic inflammatory pelvic diseases.

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- **Reduce Muscle Spasm**
- **Decrease Joint Stiffness**
- **Contractures**
- **Increase Blood Flow**
- **Chronic Inflammatory Conditions**
- **Bursitis**
- **Tenosynovitis**
- **Synovitis**
- **Chronic Inflammatory Pelvic Disease**

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K063433