K973223

# 510(k) Summary

FEB 18 1998

# Stellar Model HS-04

Common/Classification Name: Powered Electrical Stimulator/ Powered Heating Pad, 21 CFR 890.5850 and 890.5740

Stellar Medical Corporation
1800 Second Street, Suite 705
Sarasota, FL 34236

Contact: B. C. James, M.D., Prepared: August 26, 1997

## A. LEGALLY MARKETED PREDICATE DEVICES

The **Stellar Model HS-04** is substantially equivalent to the RS Medical Model RS-4M (K953136) and the Staodyn EMS+2 (K926510) electrical stimulators with respect to its stimulation functions and is substantially equivalent to the PT-PAC Portable Heating Pad (K963887)with respect to its heating functions.

## B. DEVICE DESCRIPTION

The Stellar Model HS-04 is a device that combines the functionality of two devices that have been classified by FDA, the powered muscle stimulator and the powered heating pad. Heat and muscle stimulation are often used at the same time by physical therapists and others to treat patients, and the HS-04 provides both therapies with a single combination device for convenience. The heating elements are contained in the same applicators that hold the stimulation electrodes.

## C. INTENDED USE

The Stellar Model HS-04 is indicated for use in repeatedly contracting muscles using pulsed electrical currents for muscle reeducation, maintaining or increasing range of motion, relaxing muscle spasms, prevention or retardation of disuse atrophy, and prevention of venous thrombosis.

## D. SUBSTANTIAL EQUIVALENCE SUMMARY

The HS-04 is a medical device, and it combines the indications for use

of the legally marketed predicate devices. The **HS-04** has the same technological characteristics as the predicate devices and these characteristics are precise enough to ensure equivalence. This premarket notification describes the characteristics of the **HS-04** in sufficient detail to assure substantial equivalence.

## E. TECHNOLOGICAL CHARACTERISTICS

The system is powered through an AC power adaptor which can accept voltages in the range 90-132 VAC and 46-63 Hz and it draws a maximum of 0.7 Amperes. The stimulator section only (no heat) can be powered temporarily with an alkaline battery.

The HS-04 uses solid state electronics to generate the stimulation waveforms and resistive DC-powered heating elements to produce the heating effect. These characteristics are the same as those of the predicate devices.

The pulse rate and intensity are settable on the controller. In the muscle stimulator mode, the pulse rate may be varied between 1 and 150 pulses per second. The stimulator pulses for five seconds and then is off for five seconds.

The pulse width of the biphasic pulses may range from 1 to 415 microseconds according to the "intensity" setting. The second of the biphasic pair of pulses follows the first by 1 millisecond. The number of pulses per second may be adjusted from 1 to 150 by adjusting a potentiometer on the back of the controller box.

Each applicator pad is rectangular in shape (3 x 3.5 inches) with a thin profile. The heating component forms the back of the pad and the stimulation electrode forms the front surface. The stimulation electrodes have a conductive solid gel which sticks to the pad and the electrical contacts on one side and to the treatment area of the patient on the other.

## F. TESTING

The Stellar Model HS-04 is being tested for electrical safety by an independent laboratory. Tests are being carried out to assure compliance with UL-2601. KMC Systems will not market the device until the electrical safety certifications have been successfully completed.

## G. CONCLUSIONS

This pre-market submission demonstrates Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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FEB 18 1998

Re: K973223
Stellar Model HS-04
Regulatory Class: II
Product Codes: IPF, IRT, and LIH
Dated: December 9, 1997
Received: December 9, 1997

Dear Dr. Athey:

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 (Premarket 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,

for 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

## STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Stellar Model HS-04

Indications For Use:

Stimulator Mode

The Stellar Model HS-04 stimulator mode is indicated for use in repeatedly contracting muscles using pulsed electrical currents for muscle reeducation, maintaining or increasing range of motion, relaxing muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, and immediate post-surgical prevention of venous thrombosis in the calf.

Interferrential Mode

The Stellar Model HS-04 interferrential mode is indicated for use in post-surgical acute pain and edema, post-traumatic acute pain and edema, reduction of inflamation, increasing local blood circulation, maintaining or increasing range of motion, and relaxing muscle spasms.

Heating Mode

The Stellar Model HS-04 heating mode is indicated for heating of a body region for the relief of minor muscular or joint pain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973223

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)