DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 6 1998

Mr. Joe Elrod
Director of Regulatory Affairs
Chattanooga Group, Inc.
4717 Adams Road
P.O. Box 489
Hixson, Tennessee 37343-0489

Re: K982828
Trade Names: Forte CPS 400 Stim and Forte CPS 200 Stim
Product Codes: GZJ, LIH, and IPF
K982829
Trade Name: Forte CPS Ultrasound
Product Code: IMI
K982830
Trade Names: Forte CPS 400 Combo and Forte CPS 200 Combo
Product Codes: GZJ, LIH, IPF, IMG, and IMI
Regulatory Class: II
Dated: August 10, 1998
Received: August 11, 1998

Dear Mr. Elrod:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) 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 devices, 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.

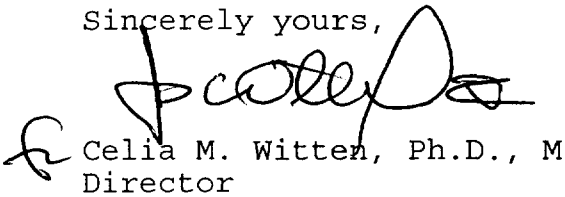
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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

Enclosures

CHATTANOOGA GROUP, INC.

STATEMENT OF INDICATIONS FOR USE

For Ultrasound

Ultrasound for use in applying deep heat can be used for treatment of selected medical conditions such as the relief of pain, muscle spasms and joint contractures. These conditions may be associated with adhesive capsulitis, bursitis with slight calcification, myositis and soft tissue injuries. The CPS Ultrasound, while using any of the applicators available for this device, can provide therapeutic deep heating between 40° and 45 °C in all of its operating modes.

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982829

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