510(k) Summary

K970051

Smith & Nephew, Inc.
DonJoy Division
2777 Loker Ave. West
Carlsbad, CA 92008

JUL 10 1997

Contact Person: Dan W. Miller

Phone: (760) 438-9091

Date Prepared: April 11, 1997

INTRODUCTION

The MuscleSense™ II is an EMG (Electromyography) device intended for medical use for muscle re-education and relaxation training. We consider the Smith & Nephew MuscleSense™ II portable EMG to be substantially equivalent to the Autogenics Systems' AT Dual Channel EMG and the Promethius Group Pathway™ MR 25 EMG System. The MuscleSense™ II, AT , and Pathway MR-25 are all indicated for relaxation training and muscle re-education. All three devices are used in conjucnction electrodes. The MuscleSense™ II tnresold sensitivity testing confirmed the device to fall within an acceptable sensitivity range to effectively monitor muscle activity. There is no electrical current being delivered to the patient. The device is supplied with pre-gelled conductive electrodes which have been cleared for marketing by the Food and Drug Administration under K851522/A. The device is battery powered or by a UL544 approved wall mounted power supply.

Smith & Nephew, Inc.
DonJoy Division

Dan W. Miller
Director, Regulatory Affairs
& Quality Assurance

SPECIFICATIONS

Input Impedance:	10^{10} Ohms
Sensitivity:	0.5 µV rms
Bandwidth:	45-300 Hz
CMRR:	115dB
Notch Filter:	60 Hz, 24dB
Input Noise:	0.28 µV
Bias Current:	5 nA
Range:	x1 0-50µV rms x10 0-500µV rms x50 0-2500µV rms
Modes:	PEAK, COUNT, RATIO
Power Source	
external:	7 Vdc wall mount supply (UL544 approved)
battery pack: (optional)	6 Vdc rechargeable NiCad battery pack
battery life:	8 hours
Dimensions	
width:	6"
length:	6"
height:	3.25"
weight:	25 oz
Storage Temperature:	-20°C to +50°C (-4°F to +122°F)
Operating Temperature:	0°C to +50°C (+32°F to +122°F)

Note: Electrical specifications are typical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Dan W. Miller
Director, Regulatory Affairs & Quality Assurance
Smith & Nephew DonJoy, Inc.
2777 Loker Avenue West
Carlsbad, California 92208-6601

JUL 10 1997

Re: K970051
Trade Name: MuscleSense II Dual Channel Electromyography Device
Regulatory Class: II
Product Code: 84HCC
Dated: April 11, 1997
Received: April 15, 1997

Dear Mr. Miller:

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) 594-4648. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(k) Number (if known): K970051

Device Name: MuscleSense II Dual Channel Electromyography Device

Indications For Use:

1) Relaxation Training
2) Muscle Re-education

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970051

Prescription Use X
(Per 21 CFR 801.109)

~~OR~~ ~~Over The Counter Use~~

(Optional Format 1-2-96)