AUG 27 1999

K990766

510(k) SUMMARY
CERSR™ Electromyography System
March 8, 1999

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k), premarket notification was in accordance with 21 CFR 807.87.

1. Applicant, Official Correspondent and Owner of 510(k)

Paraspinal Diagnostic Corporation
1275 Kinnear Road, Suite 135
Columbus, Ohio 43212

Attn:: Richard L. Hitchcock, Vice President of Operations
Telephone: (614) 487-3652
Fax (614) 487-3642

2. Name of Device

Trade/Proprietary Name: CERSR™ Electromyography System

Common/Usual Name: Electromyographic System

Classification Name: 21 CFR 890.1375 "Diagnostic Electromyograph", Class II.

3. Legally Market Predicate Devices

The CERSR is substantially equivalent[1] to legally marketed predicate devices including:

- Synergy Multimedia EMG/EP, Teca Corporation;
- Advantage 3000 series, Advantage Medical Division of CME Telemetrix;
- Sierra Console, Cadwell Laboratories;
- Compass PortaBook II, Nicolet Biomedical.

[1] Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to refer to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. (Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355))

4. Indications for Use

The CERSR™ Electromyography System is used to monitor and display the bioelectric signals produced by muscles to aid in the diagnosis and prognosis of muscular disease or dysfunction.

5. Device Description and Substantial Equivalence

CERSR™ is an electromyography system. CERSR™ is substantially equivalent[2] to legally marketed predicate electromyographic systems. Like most electromyographic systems, CERSR™ allows for the monitoring and displaying of the bioelectrical signals generated by muscles.

CERSR™ is specifically designed for a real-time recording of muscle electrophysiology. Most electromyographic systems have at most five channels for monitoring and displaying the activity of several muscles or muscle groups simultaneously. The CERSR™ reduces the problems associated with too few channels and allows for a real-time recording from multiple locations by applying an array of surface electrodes over the anatomical region of interest. Each electrode is connected to its own channel with preamplifier, amplifier, buffers and filters. The CERSR™ produces a user display of the myoelectric signals. These recordings may viewed in one of three standard formats, as a typical waveform, RMS display or as a frequency spectral analysis plot.

In conclusion, relevant to the issue of substantial equivalence, the CERSR™ system has the same technological characteristics as legally marketed predicate devices. That is, the technological characteristics of the CERSR™ and the predicate devices are those necessary to accurately record, and monitor bioelectric signals of the target muscles and display these signals in standard formats including normal waveforms, RMS values and FFT spectrally analyzed plots.

---

[2] Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to refer to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. (Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355))

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 1999

Paraspinal Diagnostic Corporation
c/o Joel S. Faden, Ph.D.
Regulatory Consultant
11605 Hitching Post Lane
Rockville, Maryland 20852

Re: K990766
Trade Name: CERSR™ Electromyography System
Regulatory Class: II
Product Code: IKN
Dated: June 14, 1999
Received: June 15, 1999

Dear Dr. Faden:

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) 594-4595. 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

Indications For Use

K990766

Device Name: CERSR™ Electromyography System

Indications For Use:

The CERSR™ Electromyography System is used to monitor and display the bioelectric signals produced by muscles to aid in the diagnosis and prognosis of muscular disease or dysfunction.

Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990766

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)