K010270

JUL 2 5 2001

510(k) SUMMARY

TREMOROMETER®

Common/Classification Name: **System, Telemetry, Physiological Signal Conditioner**

FlexAble Systems, Inc.
16410 East Tombstone Avenue
Fountain Hills, AZ 85268-6545.

Contact: **Robert M. Tripp, Ph. D., President**

Preparation Date: **January 12, 2001**

A. LEGALLY MARKETED PREDICATE DEVICES

The **Tremorometer®** is substantially equivalent to the legally marketed **Axiom or FlexiPlus™** and/or the **Actiwatch®** devices.

B. DEVICE DESCRIPTION

The Tremorometer is a system designed to improve the measurement and quantification of tremor in human patients regardless of the underlying etiology of the tremor. It consists of a Tremor Sensor, a microcomputer and programs to operate the microcomputer. The federally registered trademark "Tremorometer" is intended to cover the system comprised of these three parts.

The Tremor Sensor is a three axis accelerometer that attaches to a patient's finger and transmits the tri-axial tremor measurements to the Tremorometer. Other acceleration measuring devices could be used in place of the current Tremor Sensor provided they met the sensitivity, accuracy, resolution and range of the current device.

The microcomputer is the FlexLab™ manufactured by FlexAble Systems, Inc. that is used in a number of industrial applications. It is a battery powered, hand-held, self-contained, programmable device. Other microcomputers with the capability of reading the pulse width modulated signals generated by the Tremor Sensor could be used in place of the FlexLab.

The programs range from general system software to control the keypad and LCD displays to proprietary algorithms that process the tremor data. The code is written in 'C' and could be easily ported to another microcomputer.

The FlexLab has a keypad and LCD display for interaction with the user. General purpose software provides for setting and reading date and time from a clock/calendar IC; bi-directional serial communication using Xmodem CRC and CSum protocols at selectable Baud rates; display and control of system settings; and more. Custom software designed specifically for the tremor measuring and processing application include routines to take precisely timed measurements from the Tremor Sensor; perform calibration of the Tremor Sensor using Earth's gravity as a reference; run automated, timed series of tests; process and store data with check digits to insure data integrity; display the data graphically on the LCD; generate and maintain record headers; control the transmission of complete records to a PC; clear records; download user generated test lists; and more.

The three-axis reading may be combined into a single composite measure of total movement by proprietary algorithms that eliminate some of the non-tremor signals such as rotational components, orientation relative to Earth's gravity and other artifacts.

C. INDICATIONS FOR USE

The Tremorometer is designed to measure a patient's tri-axial tremor movements.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The Tremorometer has the same indications for use as the legally marketed **Axiom or FlexiPlus™** (referred to as the FlexiPlus) and/or the **Actiwatch®** devices. The Tremorometer has the same technological characteristics as the legally marketed **FlexiPlus™** and/or the **Actiwatch®** devices. However, the characteristics may not be sufficiently precise to assure equivalence. Therefore, FlexAble Systems, Inc. has carried out validation and performance testing. The results of this testing documents that the Tremorometer performs as well as the legally marketed **FlexiPlus™** and/or the **Actiwatch®** devices.

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Tremorometer are very similar to those of the legally marketed **FlexiPlus™** and/or the **Actiwatch®** devices. The similarities and differences include:

Characteristic	FlexiPlus™	Actiwatch	Tremorometer
Measures muscle testing	Yes	No	No
Measures occurrence and degree of motion	No	Yes	No
Measures tremor	No	No	Yes
Attaches to arm	Yes	No	Yes
Attaches to wrist	No	Yes	Yes
Attaches to finger	No	No	Yes
Battery operated	Yes	Yes	Yes
Stores measured data internally	Yes	Yes	Yes
Amplifies data	Yes	Yes	Yes
Proprietary software analyses data	Yes	Yes	Yes
Downloads collected data to PC	Yes	Yes	Yes

F. TESTING

The Tremorometer device has undergone extensive alpha and beta testing. Beta testing included testing at a variety of study centers conducted by qualified researchers operating under current and valid IRBs, informed consent and protocols coordinated by Robert M. Tripp, Ph.D., and Michael P. Caligiuri, Ph.D. a qualified Scientific Investigator.

The Tremorometer software was subjected to internal verification and validation testing, the results of which are documented in this submission.

The accessory software and third-party software used in combination with this device and the data created by this device has been subject to validation and comparison to other data management system.

G. CONCLUSIONS

The validation studies document that the Tremorometer is substantially equivalent to the legally marketed **FlexiPlus™** and/or the **Actiwatch®** devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2001

Robert M. Tripp, Ph.D.
President
Flexable Systems, Inc.
16410 E. Tombstone Avenue
Fountain Hills, Arizona 85268

Re: K010270
Trade/Device Name: Tremorometer®
Regulation Number: 882.1400
Regulatory Class: II
Product Code: GWQ
Dated: April 24, 2001
Received: April 27, 2001

Dear Dr. Tripp:

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 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). 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 requirements, 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K010270

Device Name: **TREMOROMETER®**

Indications For Use:

The Tremorometer is designed to be used to measure and record tri-axial readings of a patient's tremor motions, to optionally combine the three axis tremor information into a single measurement of total tremor movement by a proprietary algorithm that eliminates some of the rotational, orientation and other artifacts, to display the information graphically, and to transfer the data to a PC for further analysis, display, printing or storage.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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

510(k) Number K010270

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