FEB 3 1998

XIV. SUMMARY OF SAFETY AND EFFECTIVENESS

TyTron C-3000 K974208

Manufacturer: Titronics Research and Development Company
2046 Redwing Hollow S.W.
Oxford, IA 52322-9112

Contact Person: Joseph Roger Titone, B.S.M.E.
Same address as above

Telephone: (319) 683-2702
Fax: (319) 683-2862

Date Summary Prepared: October 26, 1997

Product Trade Name: TyTron C-3000

Common Name: Computer Aided Paraspinal Thermographic Scanning System

Classification: Powered direct-contact temperature measurement device

Neurological Devices Classification Panel

21 Code of Federal Regulations 882.1570

Class: II

Panel: 84

Procode: 84HCS

Predicate Device: Thermatrax submitted by Artronics K-950986

Description:

The TyTron C-3000 is a hand held paraspinal thermographic scanning system. It consists of two probes which each contain infrared sensors designed to be placed on either side of the spinal column to detect temperatures. With the aid of a computer assisted program the system is capable of recording and graphing thermal differentials (right to left thermal asymmetries) on a horizontal scale. It also records direct temperatures on the vertical scale.

Indications For Use:

The TyTron C-3000 is indicated for use in detecting, measuring, recording, and graphing the skin surface temperature on both sides of the spine of adults and children by professional health care providers. It is to be used before and after therapy is rendered as part of monitoring the patient's response to care.

Substantial Equivalence:

The TyTron C-3000 is substantially equivalent to Thermatrax in that it provides the following characteristics:

-Thermocouple material used in the sensors
-Physical characteristics are essentially the same
-Material composition is essentially the same
-Same indications for use
-Same presentation of paraspinal temperature data
-Both use microprocessors to process data
-Both powered by isolated low voltage power supplies

Summary of Testing:

Test	**Thermatrax**	**C-3000**
Accuracy	± 1°C	± 1°C
Orientation of sensors	parallel , 2" centers	parallel , 1.85" centers
Filtering circuit	yes	yes
Sensitivity	± 0.05°C	± 0.01°C
Reproducibility	± 0.10°C	± 0.05°C
Accuracy, odometer	not applicable	± 0.25 cm
Sensor Wavelength	must contact skin	6 - 14 micrometers

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 1998

Mr. Joseph R. Titone, BSME
President
Titronics Research & Development Company
2046 Redwing Hollow S.W.
Oxford, Iowa 52322

Re: K974208
Trade Name: Tytron C-3000
Regulatory Class: II
Product Code: HCS
Dated: October 28, 1997
Received: November 10, 1997

Dear Mr. Titone:

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 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) 594-4595. 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

K974208

IX. INDICATIONS FOR USE

The TyTron C-3000 is indicated for use in detecting, measuring, recording, and graphing the skin surface temperature on both sides of the spine of adults and children by chiropractors. It is to be used before and after therapy is rendered as part of monitoring the patient's response to care, similar to a common thermometer. (Exhibit K - COMMENTS ON THE CLINICAL APPLICATION OF THE C-3000)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974208