K032471

Titronics Research & Development Co. TyTron C-500IR
CLINICAL INFRARED IMAGING SYSTEM
PREMARKET NOTIFICATION 510(k)

OCT 1 0 2003

XIV. SUMMARY OF SAFETY AND EFFECTIVENESS

TyTron C-3000

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: Fax:	(319) 683-2702 (319) 683-2862
Date Summary Prepared:	June 14, 2003
Product Trade Name:	TyTron C-500IR Clinical Infrared Imaging System
Common Name:	Clinical Thermographic Imaging System
Classification:	Telethermographic system Obstetrics/Gynecology Classification Panel 21 Code of Federal Regulations 884.2980 Class: I Panel: 90 Procode: 90 LHQ
Predicate Device:	Spectrum 9000MB, submitted by Telesis Technologies, Inc. K020783.
Description:	The TyTron C-500IR is a non-contact, non-invasive, non-radiating, thermal (infrared) imaging system composed of an infrared camera which is interfaced to a computer with the intent of viewing and digitally storing thermal patterns generated by the surface of the human body. The computer facilitates

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2003

Mr. Joseph R. Titone, BSME
President
Titronics Research & Develpoment Co.
2046 Redwing Hollow S.W.
OXFORD IA 52322-9112

Re: K032471
Trade/Device Name: TyTron C-500IR Clincial Infrared Imaging System
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic system
Regulatory Class: I
Product Code: 90 LHQ
Dated: August 4, 2003
Received: August 11, 2003

Dear Mr. Titone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

IX. INDICATIONS FOR USE

The TyTron C-500IR Clinical Infrared Imaging System is intended for adjunctive diagnostic screening for the detection of breast cancer and other uses such as: peripheral vascular disease, neuromusculoskeletal disorders, extracranial cerebral and facial vascular disease, thyroid gland abnormalities, and various other neoplastic, metabolic, and inflammatory conditions. Use of the TyTron C-500IR System is not intended to be the sole diagnostic procedure for these diseases and conditions.

Prescription Use ✓

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032471