

FEB 5 1999

SECTION 2

SUMMARY AND CERTIFICATION

510(k) SUMMARY

Submitted by: Trex Medical Corporation, Bennett Division
Address: 445 Oak Street, Copiague, NY 11726
Phone: (516) 691-6100, (516) 691-6103 (fax)
Contact: Lim Cheung
Device Name: Bennett Profile 2000 Mammography System, Model PRO-2000
Equivalent Device: Bennett Profile Mammography System, Model M-PRO (#K964576),
LORAD M-IV, Instrumentarium Alpha IQ, GE Senographe 800T, and
Planmed Sophie Classic
Date: November 13, 1998

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 as promulgated in 59 FR 64287-01 for §807.92.

1. *Description of the Device:* The Bennett Profile 2000 Mammographic System, Model PRO-2000, is a dedicated mammographic imaging system used as an x-ray source in the performance of mammographic examinations. The PRO-2000 is adaptable to performing screening and/or biopsy procedures with the addition of either a film-based or digital-based image receptor device attached. It consists of the following components; an x-ray generator cabinet, Model M-2000G (single-phase input) or Model M-2000G-3P (three-phase input); a tube stand with a non-tilting c-arm; mammographic collimator (DM-2000) and tube; an operator control panel, Model M-2000C; and image receptor (film cassette holder or bucky).

The Profile 2000 Mammography System is a microprocessor-controlled x-ray source requiring single-phase 200-240 VAC, 50/60 Hz or three-phase 208-440 VAC, 50/60 Hz for operation. The Profile 2000 system's c-arm is fully counterbalanced and is locked in position using electro-mechanical locks. The c-arm has a fixed source-to-image distance (SID) of 76 cm.

2. *Same Intended Use:* The Bennett Profile 2000 Mammography System (Model PRO-2000), like the Bennett Profile M-PRO, LORAD M-IV, Instrumentarium Alpha IQ, GE Senographe 800T, and Planmed Sophie Classic mammographic imaging systems, is a dedicated mammographic imaging system used for mammographic examinations.

The Bennett Profile 2000 Mammography System is substantially equivalent to currently marketed devices in terms of basic features, operation, and functionality. The safety functions of the Profile 2000 Mammography System have been rigorously tested and analyzed for conformance to requirements. In each case, these functions have performed as required, ensuring that each identified hazardous condition would not occur under simulated conditions. The Profile 2000 Mammography System fulfills its design requirements by providing the operator with the ability to perform safe and effective mammographic examinations.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 5 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Walter F. Schneider
President
Trex Medical Corporation
Bennett Division
445 Oak Street
Copiague, NY 11726

Re: K984092
Bennett Profile 2000 Mammography System
Model PRO-2000
Dated: November 13, 1998
Received: November 16, 1998
Regulatory class: II
21 CFR 892.1710/Procode: 90 IZH

Dear Mr. Schneider:

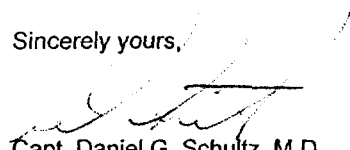
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,


Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: PROFILE 2000 MAMMOGRAPHY SYSTEM,
MODEL PRO-2000

Indications for Use:

THE PROFILE 2000 MAMMOGRAPHY SYSTEM, MODEL PRO-2000, IS A DEDICATED MAMMOGRAPHIC IMAGING SYSTEM USED FOR MAMMOGRAPHIC EXAMINATIONS.

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

Concurrence of CDH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-95)

David A. Segura
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number

K984092