K964576

BENNETT Subsidiary of
Trex Medical Corporation

JAN 10 1997

SECTION 2

SUMMARY AND CERTIFICATION

510(k) SUMMARY

Submitted by:	Bennett Subsidiary of Trex Medical Corporation
Address:	445 Oak Street, Copiague, NY 11726
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Contact:	John A. Shovary
Device Name:	Bennett Profile Mammography System, Model M-PRO
Equivalent Device:	Bennett Contour Mammography System, Model M-CTR (#K925725), LORAD M-IV, Instrumentarium Alpha RT, GE Senographe 700T and 800T, and Philips mammo DIAGNOST 3000
Date:	November 8, 1996

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 Mammographic System, Model M-PRO, is a dedicated mammographic imaging system used as an x-ray source in the performance of mammographic examinations and can be adapted for biopsy and spot mammographic examinations. It consists of the following components; an x-ray generator cabinet, Model M-1500G; tube stand with non-tilting C-arm; mammographic collimator (DM-1500) and tube; an operator control panel, Model M-1500C; and image receptor (film cassette holder or bucky).
   The Profile Mammography System is a microprocessor-controlled x-ray source requiring single-phase 200-240 VAC, 50/60 Hz for operation. The Profile 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 mammography system, like the Bennett Contour M-CTR, LORAD M-IV, Instrumentarium Alpha RT, GE Senographe 700T and 800T, and Philips mammo DIAGNOST 3000 mammographic imaging systems, is a dedicated mammographic imaging system used for mammographic examinations.

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The Bennett Profile Mammography System is substantially equivalent to currently marketed devices in terms of basic features, operation, and functionality. The safety functions of the Profile 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 Mammography System fulfills its design requirements by providing the operator with the ability to perform safe and effective mammographic examinations.

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