

AUG - 6 1999

K992229

510 (k) SUMMARY

I GENERAL INFORMATION:

Establishment -

- Address: Trex Medical Corporation  
LORAD Division  
36 Apple Ridge Road  
Danbury, CT 06810
- Contact Person: Kelvin Burroughs  
Regulatory Affairs  
Telephone- 203 790 1188  
Fax- 203 743 3370

Device Name - MXU-125 or TMX-125 Mobile X-ray Unit

II PERFORMANCE STANDARD: 21 CFR Subchapter J

All system components to which the above standard applies are certified to conform to 21 CFR Subchapter J (21 CFR 1020.30, 1020.31 and 1020.32 Diagnostic X-ray Equipment Standard)

III SUBSTANTIAL EQUIVALENCE:

The Mobile X-ray Unit has similar technological characteristics and intended uses as the predicate devices below.

TREX Medical Corp. believes the Mobile X-ray Unit is substantially equivalent to the following medical devices:

<u>Model</u>	<u>Company</u>	<u>FDA 510 (k)</u>
RT-125	Lorad Medical Systems Inc.	K894643
AMX-3	GE Medical Systems	K902610

III Indications for Use:

The MXU-125 or TMX 125 is a Mobile x-ray Unit intended for use in general radiographic medical procedures by a licensed professional.

IV TECHNOLOGICAL CHARACTERISTICS:

The Mobile X-ray Unit is a portable, battery-powered, self-propelled unit designed for making film radiographs in a hospital environment. The unit is capable of generating diagnostic x-rays according to the technique factor combinations selected and controlled by the operator.

The Unit complies with Part 1020, Performance Standards for Ionizing Radiation Emitting Products and conforms to recognized voluntary standards for electrical safety, electromagnetic compatibility of medical equipment and radiation safety.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 6 1999

Kelvin Burroughs  
Regulatory Affairs  
TREX Medical Corporation  
Lorad Division  
36 Apple Ridge Road  
Danbury, Connecticut 06810

RE: K992229  
MXU-125 or TMX-125 Mobile X-ray Unit  
Dated: June 29, 1999  
Received: July 2, 1999  
Regulatory Class: II  
21 CFR 892.1720/Procode: 90 IZL

Dear Mr. March:

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

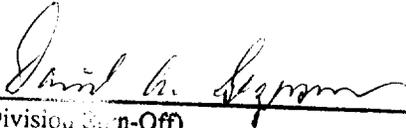
510(k) Number (if known): \_\_\_\_\_

Device Name: LORAD MXU-125 or TMX-125 Mobile X-ray Unit

Intended Use:

The MXU-125 or TMX-125 is a Mobile ray unit intended for use in general radiographic medical procedures by a licensed professional.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K992229

Prescription Use  ✓  
21 CFR 801.109

OR

Over-the-Counter Use  \_\_\_\_\_

**ORIGINAL**