



Mr. William Cousins
Vice President, Regulatory Affairs
TREX Medical Corporation
Continental Subsidiary
2000 South 25th Avenue
BROADVIEW IL 60153

MAY - 7 2012

Re: K982427

Trade/Device Name: TREX Tilt-C, Integrated C-Arm/Table Multipurpose
Radiographic/Fluoroscopic Positioning System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: July 2, 1998
Received: July 2, 1998

Dear Mr. Cousins:

This letter corrects our substantially equivalent letter of September 23, 1998.

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

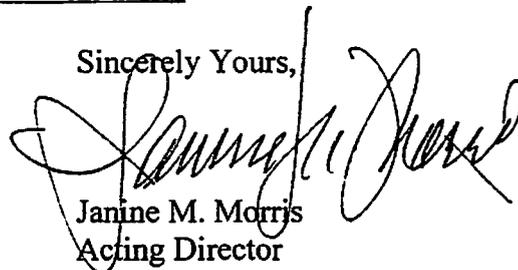
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris". The signature is fluid and cursive, with a large initial "J" and "M".

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATION OF USE

Re: "Indication For Use" page, for 510(K) Premarket Notification Submission for
TREX Tilt-C, Integrated C-Arm/Table multipurpose radiographic/fluoroscopic
positioning system

510(k) Number: _____

Device Name:

Integrated C-Arm/Table multipurpose radiographic/fluoroscopic positioning system,
Model TREX Tilt-C.

Indication For Use:

TREX Tilt-C, Integrated C-Arm/Table multipurpose radiographic/fluoroscopic positioning
system. It is an all-digital multi-purpose system designed to address a broad variety of
radiographic/fluoroscopic, interventional and limited angiographic procedures.

TREX Medical Corporation,
CONTINENTAL Division



Oscar Khutoryansky,
Vice President, Engineering

July 2, 1998

Concurrence of the CDRH, Office of Device Evaluation (ODE)

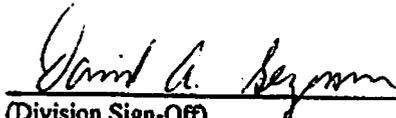
Concurrence of SDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Optional Format 1-2-96



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

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