OCT - 5 1993

K933431

Summary of Safety and Effectiveness

I. General Information

Classification:	Class II 21 CFR 892.1720 Mobile X-Ray System Accessory
Common Name:	Mobile C-Arm Accessory
Device Trade Name:	Orthotrac Coaxial Laser System
Establishment Name and Address:	TRAC Medical, Inc. 4106 Wake Forest Road Raleigh, NC 27609
Establishment Registration Number:	In process of filing
Performance Standards:	Federal Diagnostic X-Ray Performance Standard Federal Performance Standard for Light Emitting Products

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

Performance Standards

All components to which the above referenced performance standards apply are certified to conform with 21 CFR Subchapter J.

Intended Use

The Orthotrac Coaxial Laser is an optional accessory designed for use with any currently marketed Mobile C-Arm unit. It does not alter the intended use of the basic C-Arm unit for routine diagnostic imaging. Its intended use and technological characteristics are also similar to those of the currently marketed OEC-Diasonics Laser Aiming Device.

Laboratory Testing

Laboratory test results have shown that the Orthotrac Coaxial Laser System is an accurate targeting device, and that its accuracy is reproducible over a number of experiments.

General Safety and Effectiveness Concerns

The device labeling contains instructions for use. The information provided in the instructions for use assures safe and effective use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Terry N. Williams
President
TRAC Medical, Incorporated
4106 Wake Forest Road
RALEIGH NC 27609

NOV 21 2011

Re: K933431
Trade/Device Name: Orthotrac Coaxial Laser
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified Fluoroscopic x-ray system
Regulatory Class: II
Product Code: OXO
Dated: June 22, 1993
Received: July 19, 1993

Dear Mr. Williams:

This letter corrects our substantially equivalent letter of October 5, 1993.

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 (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. Please Note: CDRH does not evaluate information related to contact liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely Yours,

Michael D Ostrow for

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure