K022114

ELMSTech, INC.
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510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Applicant

ELMSTECH, INC.
950 JERICHO TURNPIKE
WESTBURY, NEW YORK
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CONTACT PERSON: ROBERT MANNERS
PRESIDENT

2. Device Identification

Proprietary Device Name:	**IMPERIUM** MOBILE C-ARM X-RAY EQUIPMENT
Common/Generic Device Name:	MOBILE C-ARM X-RAY EQUIPMENT
Classification Name:	SYSTEM, X-RAY, MOBILE
Product Code:	OWB, JAA & OXO
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.1720 + 892.1650

3. *Substantial Equivalence*

The **IMPERIUM** MOBILE C-ARM X-RAY EQUIPMENT is substantially equivalent to the following currently marketed devices:

- GE OEC 9800 PLUS (K021049)
- SIEMENS MEDICAL SIREMOBIL ISO-C (K973598)

4. *Description of Device*

The **IMPERIUM** is a mobile c-arm x-ray imaging equipment consisting of a c-arm stand and a monitor trolley. The c-arm stand holds the high-frequency x-ray generator, x-ray tube assembly, x-ray controls, image intensifier and TV camera. Monitor trolley supports the image display monitors, image processing and recording devices.

The **IMPERIUM** is designed to provide the user with smooth linear and rotational movements around patient without need of further reorientations. The C-arm movements are fully motorized for ease of operation.

The **IMPERIUM** is designed according to such principles as lower dosage, better image quality and manipulation, workflow enhancement, operator and patient comfort and versatility. The IMPERIUM can be operated at Fluoroscopy, Pulsed Fluoroscopy, Digital Radiography, Cassette Radiography, Digital Subtraction Angiography (DSA) and Roadmap modes. Image processing and storage capabilities such as last image hold, recursive filtering, real time edge enhancement, real time zooming, image reversal, continuous image rotation, radiation-free collimation and contrast/brightness adjustment are possible under user control.

5. *Intended Use*

The **IMPERIUM** is intended to provide fluoroscopic and radiographic imaging of the patient during diagnostic, surgical and interventional procedures. Clinical applications may include but are not limited to digital subtraction angiography (DSA), orthopedic, neurologic, abdominal, vascular, cardiac, critical care and emergency room procedures. The system may be used for other imaging applications at physician's discretion.

6. *Technological Characteristics*

The **IMPERIUM** employs the same technological characteristics as the predicate devices. This device is intended for the same applications as the currently

marketed predicate devices. All systems are image intensified mobile c-arm x-ray imaging systems with fluoroscopic and cassette exposure capabilities. Like the predicate devices, **IMPERIUM** consists of a c-arm stand, and standard system components: x-ray generator, x-ray tube, Image Intensifier, TV system and a monitor trolley.

The IMPERIUM is designed to give the best movement controls to the operator for quick and accurate imaging of the patient in order to save the dose and time. The orbital movement range of c-arm is 190°. The horizontal travel range is 20 cm and vertical travel range is 40 cm. The horizontal swivel range is ±12.5°. A large c-arm depth of 78 cm provides the user with comfortable patient access for the examinations. The image intensifier can be moved in up/down direction independently up to 20 cm to have less source-to-image intensifier distance. With this feature user can concentrate better on a specific region of interest while decreasing the dose applied and getting a better image quality.

- Isocentric C-arm
- Wide Orbital Angle range of 190°
- Large x-ray tube to image intensifier distance of 78 cm
- Independent source to image intensifier distance adjustment of 20 cm
- Fully motorized movements

7. Standards

The **IMPERIUM** is designed in accordance with the national and international product safety and performance requirements established in the following standards given in Table-1:

21 CFR 1020.30-32	FEDERAL PERFORMANCE STANDARD FOR DIAGNOSTIC X-RAY SYSTEMS
ANSI/NFPA 70&99	NATIONAL ELECTRICAL CODE and STANDARD for HEALTHCARE FACILITIES
UL 2601	MEDICAL ELECTRICAL EQUIPMENT
CSA-C22.2 No. 601.1-M90	MEDICAL ELECTRICAL EQUIPMENT
IEC 60601-1-1	Medical Electrical Equipment-Part 1 General Requirements for Safety" with Ammend 1 and 2
IEC 60601-1-2	Medical Electrical Equipment-Part 1 General Requirements for Safety-2. Collateral Standard: Electromagnetic Compatibility-Requirements and Tests

IEC 60601-1-3	Medical Electrical Equipment-Part 1 General Requirements for Safety-3. Collateral Standard: General Requirements for radiation protection in diagnostic x-ray equipment
IEC 60601-2-7	Medical Electrical Equipment-Part 2 Particular Requirements for the Safety of high-voltage generators of diagnostic x-ray generators
IEC 60601-2-28	Medical Electrical Equipment, X-Ray Tubes and X-Ray Source Assemblies
IEC 60601-2-32	Medical Electrical Equipment-Part 2 Particular Requirements for the Safety of associated equipment of x-ray equipment

Table-1 Product Performance and Safety Standards

Results of performance and compliance testing conducted at manufacturing facility and independent test organizations on **IMPERIUM** system, indicates conformance to all applicable performance standards promulgated by FDA for these systems.

8. Conclusion

Based on the comparison to other devices in technological characteristics and intended use, the **IMPERIUM** c-arm mobile x-ray imaging system is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

ELMSTech, Inc.
% Mr. Tim Mangeruga
Legal Assistant
Manners & Associates, P.C.
950 Jericho Turnpike, Suite 100
WESTBURY NY 11590-1597

MAY 22 2012

Re: K022114
Trade/Device Name: Imperium Mobile C-arm X-Ray System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA and OXO
Dated: June 21, 2002
Received: June 28, 2002

Dear Mr. Mangeruga:

This letter corrects our substantially equivalent letter of November 14, 2011.

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,

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

STATEMENT OF INDICATIONS FOR USE

Applicant: ELMSTECH, INC.

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510(k) NUMBER: K022114

DEVICE NAME: IMPERIUM MOBILE C-ARM X-RAY IMAGING EQUIPMENT

INDICATIONS FOR USE:

The **IMPERIUM** is intended to provide fluoroscopic and radiographic imaging of the patient during diagnostic, surgical and interventional procedures. Clinical applications may include but are not limited to digital subtraction angiography (DSA), orthopedic, neurologic, abdominal, vascular, cardiac, critical care and emergency room procedures. The system may be used for other imaging applications at physician's discretion.

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022114