APR 2 7 2005

510(k) Summary K050866

Centrion 500 C-Arm System

Classification Name: Image-Intensified Fluoroscopy Device
21 CFR 892.1650

Companiy. OsteoSys

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Contact: :Henry Jang, Prepared: December 15, 2004

A. LEGALLY MARKETED PREDICATE DEVICE

The Centrion 500 C-Arm System is substantially equivalent to the General Electric OEC FLEXIVIEW 8800 Digital Mobile Imaging System (K003837).

B. DEVICE DESCRIPTION

The **Centrion 500 C-Arm System**. Is a digital C-Arm-type fluoroscopic system. It includes nearly every feature that exists on currently marketed products, with improvements on many, while enclosing those features in a more compact system, and adding a Real-Time Pulsed Fluoroscopy mode. The Real-Time Pulsed Fluoroscopy mode can significantly reduce the dose to the patient, without compromising image quality. Dose reductions of up to 85% are possible.

C. INTENDED USE

The Centrion 500 C-Arm System is designed to provide fluoroscopic and spot-film imaging of the patient during diagnostic and surgical procedures. Clinical applications include, but are not limited to, general surgery, gastro-intestinal, urologic, orthopedic,neurologic, vascular, and emergency room procedures. The system may be used for other imaging applications at the physician's discretion.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **Centrion 500 C-Arm System** is a medical device, and it has the same indications for use as the legally marketed predicate device. The **Centrion 500 C-Arm System** has the same technological characteristics as the predicate devices. This premarket notification has described most

characteristics of the **Centrion 500 C-Arm System** in sufficient detail to assure substantial equivalence.[1] For a few characteristics, such as electrical safety, testing to the requirements of consensus standards was carried out to assure equivalence

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the proposed and predicate devices are the same. Both use a digital image receptor and standard image manipulation software tools to display real-time digital fluoroscopic images.

F. TESTING

The device was tested to the requirements of the following several standards that pertain to x-ray devices:

IEC-60601-1-3 – General Requirements for Radiation Protection in Diagnostic X-Ray Equipment.

IEC-60601-2-7 – Particular Requirements for the Safety of High-Voltage Generators of Diagnostic X-Ray Generators

IEC-60601-2-28 – Particular Requirements for the Safety of X-Ray Source Assemblies and X-Ray Tube Assemblies for Medical Diagnosis.

IEC-60601-2-32 – Particular Requirements for the Safety of Associated Equipment of X-Ray Equipment.

21 CFR 1020

G. CONCLUSIONS

This pre-market notification has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

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[1] The meaning of the terms "substantial equivalence" and "substantially equivalent" as used in this 510(k) is limited to the way they are defined in, and used by FDA in accordance with, Sections 513(f)(1) and 513(I)(1) of the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2005

OsteoSys.
% T. Whit Athey, Ph.D.
Senior Consultant
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BROOKVILLE MD 20833-2233

Re: K050866
Trade/Device Name: Centrion 500 C-Arm System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: April 5, 2005
Received: April 5, 2005

Dear Dr. Athey:

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 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 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050866

Device Name: Centrion 500 C-Arm System

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050866