K110069 (1/2)

FEB - 8 2011

We are **smith&nephew**

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	January 7, 2011
Contact Person and Address:	Shereen Myers, Regulatory Affairs Specialist T (901) 399-6325 F (901) 566-7075
Name of Device:	Smith & Nephew, Inc. Spatialframe.com Software version 4.1
Common Name:	Multilateral Fixators and Accessories
Device Classification Name and Reference:	21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories.
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	KTT/OSN

Device Description

Subject of this Special 510(k) premarket notification is the Smith & Nephew Spatialframe.com version 4.1 Software. The subject device is a web-based software component of a multilateral external fixation system that is intended for fracture fixation, fixation of long bones and for joint fusions and limb lengthening or deformity corrections which involve cutting of the bone. The software is designed to be used to assist the physician in adjusting the external fixator frame by creating a patient adjustment schedule. The Spatialframe.com software receives inputs measurements taken by the physician and produces outputs recommending adjustments to the fixator that define a correction path for the deformity.

Technological Characteristics

A review of the mechanical data indicates that the hardware components of the Circular Fixation System are capable of withstanding expected in vivo loading without failure. In addition, software verification and validation testing was completed in line with FDA's guidance document entitled, "General Principles of Software Validation; Final Guidance for Industry and FDA Staff," dated January 11, 2002. The following software testing of the Spatialframe.com v4.1 software was performed:

- Software Installation Qualification Protocol
- Software Operational Qualification Protocol
- Software Performance Qualification Protocol

The results of the testing indicate that the software will perform as intended. A review of this testing has demonstrated that there are no new issues related to the safety and effectiveness of the subject device. Clinical data was not needed to support the safety and effectiveness of the subject device.

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Intended Use

The Smith & Nephew Spatialframe.com software is intended to be used as a component of multilateral external fixation systems that are indicated for the following: post-traumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; open and closed fracture fixation; pseudoarthrosis of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformities; correction of bony or soft tissue defects; joint arthrodesis; infected fractures or nonunions.

Substantial Equivalence Information

The substantial equivalence of the Spatialframe.com Software version 4.1 is based on its similarities in indications for use, design features, and operational principles to the predicate system listed in the table below.

Table 1: Substantially Equivalent Predicate System

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Circular Fixation System	K093047	09/27/2010

Conclusion

As previously noted, this Special 510(k) Premarket Notification is being submitted to request clearance for the Spatialframe.com Software, version 4.1. Based on the similarities to the predicate component and a review of the validation testing performed, the device is substantially equivalent to above predicate system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith and Nephew Endoscopy, Inc.
% Ms. Shereen Myers
Regulatory Affairs Specialist
1450 E Brooks Road
Memphis, Tennessee 38116

FEB - 8 2011

Re: K110069
Trade/Device Name: Smith & Nephew Spatialframe.com version 4.1
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT, OSN
Dated: January 7, 2011
Received: January 10, 2011

Dear Ms. Myers:

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 (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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K110069

Device Name: Smith & Nephew Spatialframe.com version 4.1

Indications for Use:
The Smith & Nephew Spatialframe.com software is intended to be used as component of multilateral external fixation systems that are indicated for the following: post-traumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; open and closed fracture fixation; pseudoarthrosis of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformities; correction of bony or soft tissue defects; joint arthrodesis; infected fractures or nonunions.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801.109) (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Merkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110069