DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 20, 2014

Smith and Nephew, Incorporated
Mr. Martin Ostmann
Regulatory Affairs Specialist II
1450 Brooks Road
Memphis, Tennessee 38116

Re: K142520
Trade/Device Name: Spatialframe.com V5.0
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: October 23, 2014
Received: October 27, 2014

Dear Mr. Ostmann:

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. Please note: CDRH does not evaluate information related to contract 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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 -S

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

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K142520

Device Name: Spatialframe.com V5.0

Indications for Use: Smith & Nephew External Fixation Systems

1. Post-Traumatic joint contracture which has resulted in loss of range of motion
2. Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
3. Open and closed fracture fixation
4. Pseudoarthrosis of long bones
5. Limb lengthening by epiphyseal or metaphyseal distraction
6. Correction of bony or soft tissue deformities
7. Correction of segmental bony or soft tissue defects
8. Joint arthrodesis
9. Infected fractures or nonunions

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)

We are smith&nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	October 22, 2014
Contact Person and Address:	Martin Ostmann Regulatory Affairs Specialist II T 901-399-1809
Name of Device:	Spatialframe.com V5.0
Common Name:	Multilateral fixators and assemblies
Device Classification Name and Reference:	21 CFR 888.3030 Single/Multiple component metallic bone fixation appliances and
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	KTT/OSN

Device Description

The Taylor Spatial Frame Spatialframe.com V5.0 includes a mobile app which is a mobile medical device that aids in the communication between a patient/caregiver and physician. The Taylor Spatial Frame external fixator relies on existing Spatialframe.com software to generate a treatment schedule for limb restoration. The new Taylor Spatial Frame mobile app (iADJUST) will allow the prescribed schedule (currently provided in paper form) to be available and viewable to the patient on a mobile device. Feedback information related to schedule adherence will be available to the physician.

No changes to the hardware of the fixation device will result from the addition of the mobile app. No changes to the treatment schedule or core functionality of Spatialframe.com software will result from the addition of the mobile app.

Indications for Use

1. Post-Traumatic joint contracture which has resulted in loss of range of motion
2. Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
3. Open and closed fracture fixation
4. Pseudoarthrosis of long bones
5. Limb lengthening by epiphyseal or metaphyseal distraction
6. Correction of bony or soft tissue deformities
7. Correction of segmental bony or soft tissue defects
8. Joint arthrodesis
9. Infected fractures or nonunion

Technological Characteristics

Software validation has been documented to ensure that the information displayed on the mobile medical app is accurate. No other changes to the existing treatment software algorithm (spatialframe.com) are included in this submission.

Substantial Equivalence Information

The proposed mobile device in Spatalframe.com V5.0 is an extension of the existing class II Spatialframe.com software. The new software is intended to be used within the same indications for use; does not make any changes to the fundamental technology of the Taylor Spatial Frame fixation device or Spatialframe.com software; and has been fully validated to ensure that it is substantially equivalent to the existing Spatialframe.com software in performance and technological characteristics. The Taylor Spatial Frame Mobile App does not alter the intended use of the existing medical device. The new mobile app is designed only to make communication of the existing treatment plan more convenient for the patient and caregiver. The Taylor Spatial Frame mobile app is substantially equivalent to the existing Spatialframe.com software.

Table 1: Substantially Equivalent Predicates to the Taylor Spatial Frame Mobile App

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Spatialframe.com version 4.1 **(Primary Predicate)**	K110069	2/8/11
Smith & Nephew, Inc.	Circular Fixation **(Reference Predicate)**	K093047	9/27/10

Conclusion

Spatialframe.com V 5.0 is substantially equivalent to the existing Spatialframe.com version 4.1 cleared in K110069, and the Circular Fixation medical device cleared in K093047 in that the indications for use for these devices are identical and the core technological principles for these devices are also equivalent.