

510(k) Summary

Device: Hip Sextant Instrument System (K093491)

Submission Type: Traditional 510(k)

DEC - 9 2010

Date Prepared [21 CFR 807.92(a)(1)]: Revised October 29, 2010

Submitter's Information [21 CFR 807.92(a)(1)]

This 510(k) is being submitted by Orchid Design on behalf of Surgical Planning Associates, Inc.

Contact:

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Sponsor / Manufacturer:

Surgical Planning Associates, Inc
43 Riverside Avenue, #192
Medford, MA 02155

FDA Establishment Registration#: Pending

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Device Trade Name: Hip Sextant

Device Common, Usual, or Classification Names:

- Orthopedic Stereotaxic System
- Acetabular cup alignment guides
- Acetubular Positioner
- Socket positioned
- Trocar

Classification: Class 2; ref. 21 CFR 21 §882.4560 (OSF – Patient Specific Manual Orthopedic Stereotaxic System).

510(k) Summary - Continued

Predicate Devices [21 CFR 807.92(a)(3)]

- Wright Medical – Acetabular Alignment Guide, Class 1 Exempt
- Depuy – Pinnacle Cup System – Class 1, Exempt
- Stryker – Acetabular Alignment Guide, Class 1 Exempt
- Aufranc Universal Cup Alignment Guide – Class 1 Exempt and Preamendment
- Protractors – Class 1 exempt and Pre-amendment

The subject device as well as the predicate devices are composed of medical grade metal and reusable. The Depuy, Stryker, and Wright Medical instruments were design to be used with hip systems from the respective manufacturers. Both the Hip Sextant and the Aufranc Universal Cup Alignment Guide can be used during any hip reconstructive procedure regardless of the type of implant being used.

Both the HipSextant device and Protractors have measurement numbers or indicators on the device to assist the surgeon with alignment. The other devices do not have such numeric indicators.

Description of the Device [21 CFR 807.92(a)(4)]

The HipSextant Instrument is a manual mechanical acetabular positioning device. The devices is used in conjunction with CT mapping of the individual patients pelvis.

The instrument has three legs which land on the pelvis. The legs form three points which define the sextant plane. The sextant has two protractors that are adjusted to orientate a direction pin in the direction of the desired orientation of the acetabular component.

During surgery a small pin is placed into the ischium and a cannulated leg and the sextant are seated onto the ischium. The second leg is seated onto the lateral side of the anterior superior spine by placing an arthroscopic style trocar through a cannula. Finally, a third leg is also seated using a trocar. With the sextant firmly docked onto the pelvis, the cup impactor is then aligned with the sextant direction pin.

The device is used with an Excel spreadsheet which is used to assist the surgeon in performing calculations regarding alignment.

Intended Use [21 CFR 807.92(a)(5)]

The Hip Sextant Instrument System is a manual surgical instrument used to align the acetabular components during hip arthroplasty procedures.

510(k) Summary - Continued

Technological Characteristics [21 CFR 807.92(a)(6)]

Surgical Planning Associates, Inc. believes that the subject device is substantially equivalent to the cited predicate devices. These types of devices are typically exempt from 510(k). However, the subject device utilizes a non-traditional plane for the navigation of acetabular cup positioning, which we believe can be appropriately reviewed under a 510(k) notification. Nevertheless, the conclusion of substantial equivalency is based on the identical indications for use, design concept, level of surgical invasiveness, and that all cited instruments are metal and reusable. Equivalence is further substantiated by clinical and non-clinical data.

Performance Data [21 CFR 807.92(b)(1)]

The subject device is composed of medical grade biocompatible materials.

The subject device has been subjected and successfully passed clinical and non-clinical testing including the following:

- Sterilization Validation
- Cleaning Validation (including protein residual)
- Repeated autoclave studies to evaluate performance and wear
- Validation of software used in conjunction with the device to perform calculations.
- Clinical experience

Conclusion [21 CFR 807.92(b)(3)]

We believe the subject device is substantially equivalent to the predicate device and conclude that the subject device is as safe and effective as the predicate devices.



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

Surgical Planning Associates
% Orchid Design
Mr. Joseph Azary
80 Shelton Technology Center
Medford, Massachusetts 02155

DEC - 9 2010

Re: K093491

Trade/Device Name: Hip Sextant Instrument System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OSF
Dated: November 05, 2010
Received: November 08, 2010

Dear Mr. Azary:

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.

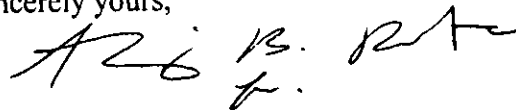
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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 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" (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/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

Indications for Use

DEC - 9 2010

510(k) Number (if known): K093491

Device Name: Hip Sextant Instrument System

Indications for Use: The Hip Sextant Instrument System is a manual surgical instrument used to align the acetabular components during hip arthroplasty procedures.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Dyke
(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

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