5. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	Evergreen Orthopedics Research Lab d/b/a Operativ 11321 NE 120th St. Kirkland, WA 98034
510(k) CONTACT:	Jeff Stepanian, COO Jeff.stepanian@opertiv.com (425) 284-7262
DATE PREPARED:	May 31, 2013
TRADE NAME:	Navigation Pin
COMMMON NAME:	Threaded Pin
DEVICE CLASSIFICATION NAME:	Stereotaxic Instrument 21 CFR 882.4560
DEVICE PRODUCT CODE:	OLO
PRODUCT CLASS:	II
SUBSTANTIALLY EQUIVALENT DEVICES:	Zimmer CAS Fixation Pins (K100599)

DEVICE DESCRIPTION:

The Navigation Pin is a partially threaded stainless steel (ASTM F138-08) pin with lengths of 100mm and 150mm. It has a diameter of 3mm. The Navigation Pins are driven into bone using a drill and collet driver. The pins hold the Stryker Navigation OrthoLock stereotaxic accessory device (6007-003-000) in place during a computer navigated total knee replacement. The Navigation Pins are placed in the distal femur and proximal tibia. Two pins are used for each Stryker Navigation OrthoLock stereotaxic accessory device (6007-003-000), one device for the femur and one for the tibia. The Navigation Pins are removed once the total knee replacement is completed. They are not meant for implanting.

TECHNOLOGICAL COMPARISON to the PREDICATE DEVICE:

The Operativ Navigation Pin is a partially threaded stainless steel pin (ASTM F138-08). The predicate device is the same material and partially threaded as well. The Navigation Pins are driven into bone using a drill and collet driver. The same technique is used for the predicate device. There are two pins that are inserted into the distal femur and two pins inserted into the medial proximal tibia. The predicate device uses the same location for their pin insertion (distal femur and medial proximal tibia). The Navigation Pins as well as the predicate device are driven into both sides of cortical bone on the femur and tibia. The threads of both the Navigation Pin and the predicate device act like a screw in the bone, holding the stereotaxic accessory device more securely. The Navigation pin has the same function/intended use that the predicate device has which is to hold stereotaxic accessory devices during total knee replacements. They are both removed from bone once the total knee replacement is complete. The differences between the Navigation Pin and the predicate device are the diameter of the pin and the length. The Navigation Pin diameter is 3mm and the predicate device is 3.2mm. The lengths of the Navigation Pin are 100mm and 150mm and the predicate device is 80mm and 150mm. Another difference is that the Navigation Pins hold the Stryker Navigation OrthoLock stereotaxic accessory device (6007-003-000) in place during a computer navigated total knee replacement. The predicate device holds their proprietary stereotaxic device in place during a total knee replacement.

INTENDED USE:

The Operativ Navigation Pin has the indication for use as a temporary fixation pin to attach an orthopedic stereotaxic tracker holder to bone. This allows the tracker to be held without movement while being referenced by the computer during a total knee arthroplasty.

CONCLUSION:

Based upon the similarities in materials (stainless steel ASTM F138-08) and design (partially threaded, trocar tip, length and diameter) as well as function/intended use (temporary fixation pin for stereotaxic device) to the predicate devices, the technological characteristics are sufficient to support a determination of substantial equivalence.

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

Evergreen Orthopedics Research Lab
d/b/a Operativ
% Jeff Stepanian, COO
11321 NE 120th Street
Kirkland, Washington 98034

July 19, 2013

Re: K131130
Trade/Device Name: Navigation Pin
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 04, 2013
Received: June 04, 2013

Dear Mr. Stepanian:

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 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. 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 -S

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

Enclosure

4. INDICATIONS FOR USE:

Device Name: Operativ Navigation Pin

Indications for Use:

Operativ Navigation Pin indication for use

The Operativ Navigation Pin is indicated for use as temporary fixation pin to attach an orthopedic stereotaxic tracker holder to bone which allows the tracker to be referenced by the computer during a total knee arthroplasty.

Prescription Use ___X___
(Part 21 CFR 801 subpart D)

Over the counter use _____
(Part 21 CFR 801 subpart C)

Joshua C. Nipper -S

(Division Sign-off)
Division of Surgical Devices
510(k) Number K131130