8. 510(k) Summary

FEB 15 2011

Date:	29 December 2010
Sponsor:	Precision Surgery Limited 2700 W. 9th Ave, Suite 120 Oshkosh, WI 54904 Phone 920-223-0547 Fax 920-223-0551
Contact Person:	Kamaljit S. Paul, MD
Proposed Trade Name:	Intuitive Anterior Cervical System
Device Classification	Class II
Classification Name:	Spinal intervertebral body fixation orthosis
Regulation:	888.3060
Device Product Code:	KWQ
Device Description:	The Intuitive Anterior Cervical System comprises plate and screw components in a variety of sizes and lengths. Three styles of plate, including fixed, variable and corpectomy, are available. Primary, self-drilling primary and rescue screws are offered.
Intended Use:	The Intuitive Anterior Cervical System is intended for anterior screw fixation of the cervical spine (C2-C7). These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system are: degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudarthrosis or failed previous fusion. WARNING: The Intuitive Anterior Cervical System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
Materials:	The Intuitive Anterior Cervical System components are manufactured from titanium alloy (Ti-6Al-4V per ASTM F136). The screw-retaining central rail is manufactured from nickel titanium alloy (NiTi per ASTM F2063).
Predicate Device:	Fixed, Variable & Corpectomy Cervical Plate System (K032815/K073708)

Technological Characteristics:	The Intuitive Anterior Cervical System identical to the predicate Fixed, Variable & Corpectomy Cervical Plate System, only the system name has changed. Therefore, the system possesses the same technological characteristics as the predicate. These include: • intended use (as described above), • design (plate-based fixation system having self-tapping screws in various sizes), • material (titanium alloy) and • sizes (plate and screw sizes are the same as those offered by the predicate system). The fundamental scientific technology of Intuitive is the same as the previously cleared device.
Performance Data:	Static compression bending and torsion, and dynamic compression bending were performed according to ASTM F1717 on a worst-case, cervical plate construct. The mechanical test results demonstrated that Intuitive performs as well as the predicate device.
Conclusion:	The Intuitive Anterior Cervical System is substantially equivalent to the devices referenced above and is therefore safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Precision Surgery, Ltd.
% BackRoads Consulting, Inc.
Karen E. Warden, Ph.D.
8202 Sherman Road
Chesterland, Ohio 44026

FEB 15 2011

Re: K103838
Trade/Device Name: Intuitive Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 29, 2010
Received: December 30, 2010

Dear Dr. Warden:

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" (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

7. Indications for Use Statement

510(k) Number: K103838

Device Name: **Intuitive Anterior Cervical System**

Indications for Use:

The Intuitive Anterior Cervical System is intended for anterior screw fixation of the cervical spine (C2-C7). These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system are: degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudarthrosis or failed previous fusion.

WARNING: The Intuitive Anterior Cervical System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Prescription Use __X__ AND/OR Over-the-Counter Use_____

(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)

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

510(k) Number K103838