510(k) SUMMARY

Hallmark Anterior Cervical Plate System Modification – Five-Level Cervical Plates

Sponsor:	Blackstone Medical, Inc. 1211 Hamburg Turnpike Suite 300 Wayne, NJ 07470
	MAY - 4 2010
Registration Number:	3004606875
Contact Person: Telephone Number: Fax Number: Email:	Darla Chew, Regulatory Affairs Director 469-742-8824 469-742-2256 DarlaChew@Orthofix.com
Submitter:	Martin Sprunck Regulatory Affairs Manger
Manufacturer:	Orthofix, Inc. 1720 Bray Central Dr. McKinney, TX 75069
Registration Number:	2183449
Contract Manufacturer:	Structure Medical, Inc. 2975 S. Horseshoe Drive Naples, Florida 34104
System Name:	Hallmark Anterior Cervical Plate System
Trade Name (Component):	Hallmark Five-Level Cervical Plates
Common Name (System):	Anterior Cervical Plate System
Product Code:	KWQ – Appliance, Fixation, Spinal Intervertebral Body
Regulatory Classification:	Class II Device, 888.3060 – *Spinal intervertebral body fixation orthosis*
Review Panel:	Orthopedic Device Panel
Predicate Devices:	Blackstone Hallmark Anterior Cervical Plate System (K050892 SE 5/11/05) Life Spine Kinetic-SL Anterior Cervical Plate System (K073479 SE 1/9/28)

Intended Use / Indications for Use

The Hallmark™ Anterior Cervical Plate System is intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies);
b) Spondylolisthesis;
c) Fracture;
d) Spinal stenosis;
e) Deformities (i.e., scoliosis, kyphosis, and/or lordosis)
f) Tumor;
g) Pseudoarthrosis;
h) Revision of previous surgery

Technological Characteristics

The Hallmark Anterior Cervical Plate System is comprised of a variety of non-sterile, single use, titanium alloy (6AL-4V ELI, per ASTM F136) components that allow a surgeon to build an anterior cervical implant construct. The system is attached to the anterior aspect of the vertebral body by means of screws to the cervical spine. The system consists of an assortment of screws, plates and associated instrumentation.

Basis of Substantial Equivalence

Mechanical evaluations were conducted to demonstrate that the Hallmark Anterior Cervical Plate System with the addition of the Five-Level Cervical Plates is substantially equivalent to predicate devices and systems that have been cleared by FDA for the purpose of building a spinal implant construct in the cervical spine.

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

MAY - 4 2010

Blackstone Medical, Inc.
% Ms. Darla Chew
Regulatory Affairs Director
1211 Hamburg Turnpike, Suite 300
Wayne, New Jersey 07470

Re: K100614
Trade/Device Name: Hallmark Five-Level Cervical Plates
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 27, 2010
Received: April 28, 2010

Dear Ms. Chew:

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K100614

System Name: Hallmark Anterior Cervical Plate System
Device Name: Hallmark Five-Level Cervical Plates

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h) Revision of previous surgery

Prescription Use __X__ (Part 21 C.F.R. 801 Subpart D) AND/OR Over-The-Counter Use____ (21 C.F.R. 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 K100614