JUL 20 2010

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Sponsor:	Biomet Spine 100 Interpace Parkway Parsippany, NJ 07054
Establishment Registration No:	2242816
Contact:	Vivian Kelly Regulatory Affairs Project Manager Biomet Spine 100 Interpace Parkway Parsippany, NJ 07054 Tel.: 973-299-9300, Ext. 2214 Fax: 973-257-0232 Email: Vivian.kelly@biomet.com
Date Prepared:	July 16, 2010
Trade/Proprietary Name:	Gallery™ Laminoplasty Fixation System
Common/Usual Name:	Appliance, fixation, interlaminal
Classification Name:	Spinal interlaminal fixation orthosis
Device Classification:	21 CFR §888.3050 Product Code: NQW
Predicate Device:	Synthes ARCH Fixation System (K032534) Blackstone Laminoplasty Fixation System (K043338)
Device Description:	The Gallery™ Laminoplasty Fixation System consists of implantable plates and screws that will act as a buttress to maintain decompression after a laminoplasty procedure.
Indications for Use:	The Gallery™ Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The Gallery™ Laminoplasty Fixation System holds or buttresses the allograft in place in order to prevent the allograft from expulsion or impinging on the spinal cord.
Summary of Technologies:	The technological characteristics of the implants and instruments comprising the Laminoplasty Fixation System are the same as or similar to the predicate devices commercially distributed.

Performance Data:

The following mechanical testing was conducted: four point bend test per ASTM F382-99, axial pullout per ASTM F543-07, and cantilever bend test as well as a detailed dimensional analysis comparing the nominal dimensions of the subject plates to its predicates. The performance data verifies that the subject device is substantially equivalent to other spinal devices currently on the market and has met all mechanical test requirements based on the worst-case construct testing and the engineering rationale.

Substantial Equivalence:

The Gallery Laminoplasty Fixation System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. Examples of predicates include the Synthes ARCH Fixation System (K032534) and Blackstone Laminoplasty Fixation System (K043338).

Conclusion:

The subject device is substantially equivalent to its predicate devices when used as a spinal fixation device. The indications for use and fundamental technology of the device remain unchanged. Furthermore, mechanical testing and other supporting information sufficiently demonstrate the substantial equivalence of the subject device to the other laminoplasty fixation devices. Based on this information, the subject device does not raise any new issues regarding the safety or efficacy.

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

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Biomet Spine
% Ms. Vivian Kelly
Regulatory Affairs Project Manager
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K100805
Trade/Device Name: Gallery™ Laminoplasty Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: July 15, 2010
Received: July 16, 2010

Dear Ms. Kelly:

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

Indications for Use

510(k) Number (if known): K100805

Device Name: Gallery Laminoplasty Fixation System

Indications for Use:

The Gallery Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The Gallery Laminoplasty Fixation System holds or buttresses the allograft in place in order to prevent the allograft from expulsion or impinging on the spinal cord.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 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 K100805

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