K083567

SEP 14 2009

Section 5: 510(k) Summary

510(k) Summary of Safety Information *Premarket Notification, Section 510(k)*	coLigne AG. July 23, 2009

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. *Device Name:*

Trade Name: ***GII-Ti-Poly-Axial Screw***
Common Name(s): Pedicle screw spinal system

Classification Name(s): Pedicle screw spinal system

2. *Establishment Name & Registration Number:*

Name: **coLigne AG.**
Number: 9614472

3. *Classification(s):*

Sec. § 888.3070 Pedicle screw spinal system

Device Class: Class II for all requested indications
Classification Panel: Orthopaedic and Rehabilitation Devices Panel
Product Code(s): MNI, MNH, KWP

4. *Equivalent Predicate Device:*

coLigne AG. believes that the ***GII Spinal Fixation System*** modified by the inclusion of the ***GII-Ti-Poly-Axial Screw*** is substantially equivalent to the screws currently offered in the ***GII Spinal Fixation System*** identified below:

K980852 – K032604 *and K051089* - *GII Spinal Fixation System*

Equivalence can be seen in the comparable design, material composition, surgical technique, intended use and testing characteristics of the GII system and other currently marketed spinal systems.

5. *Device Description:*

The new ***GII-Ti-Poly-Axial Screw*** is intended to be used with the existing components, nuts, washers, cross-links and instrumentation as currently provided with the cleared ***GII Spinal Fixation System.*** The previously cleared indications for use of the ***GII Spinal Fixation System*** are unchanged.

Testing Summary. Testing is complete. Samples were tested according to accepted engineering and scientific principals. Test results demonstrate that the new ***GII-Ti-Poly-Axial Screw*** performs in a manner equivalent to the existing screw components of the cleared ***GII Spinal Fixation System***.

Indications For Use

The GII spinal fixation system when used as a pedicle screw system in the non-cervical posterior spine, the GII spinal fixation system is to be used in skeletally mature patients as an adjunct to fusion using autograft and/or allograft for one or more of the following:

(1) Degenerative or severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar/first sacral (L5-S1) joint with objective evidence of neurologic impairment,
(2) Fracture,
(3) Dislocation,
(4) Scoliosis,
(5) Kyphosis,
(6) Spinal tumor, and/or
(7) Failed previous fusion (pseudoarthrosis).

The GII spinal fixation system when used as a hook and sacral/iliac screw fixation system in the non-cervical posterior spine, the GII spinal fixation system is to be used in skeletally mature patients as an adjunct to fusion using autograft and/or allograft for one or more of the following:

(1) Degenerative spondylolisthesis with objective evidence of neurologic impairment,
(2) Fracture,
(3) Dislocation,
(4) Scoliosis,
(5) Kyphosis,
(7) Spinal tumor, and/or
(8) Failed previous fusion (pseudoarthrosis).

6. Applicant Name & Address:

coLigne AG
Utoquai 43
Zurich, Switzerland 8008
41-433-438000
41-433-438009 – fax
Registration Number: 9614472

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

SEP 14 2009

Co-Ligne AG
% Buckman Company, Inc.
Mr. David W. Schlerf
2800 Pleasant Hill Road
Suite 175
Pleasant Hill California 94523

Re: K083567
Trade/Device Name: GH Spinal Fixation System – Ti-Poly-Axial Screw
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI, KWP
Dated: July 25, 2009
Received: September 10, 2009

Dear Mr. Schlerf:

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

510(k) Number : K083567

Device Name(s): ***GII Spinal Fixation System – Ti-Poly-Axial Screw***

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The GII spinal fixation system when used as a hook and sacral/iliac screw fixation system in the non-cervical posterior spine, the GII spinal fixation system is to be used in skeletally mature patients as an adjunct to fusion using autograft and/or allograft for one or more of the following:

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(5) Kyphosis,
(7) Spinal tumor, and/or
(8) Failed previous fusion (pseudoarthrosis).

Prescription Use X OR Over-The-Counter Use _____

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen S. Burns for MXM

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

(Per 21 CFR 801.109) (Optional format 1-2-96)

510(k) Number K083567