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JUN 24 2008

510(k) Summary Information *Premarket Notification, Section 510(k)*	coLigne AG. May 7, 2008

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

1. *Device Name:*

Trade Name: ***OstaPek® VBR System***

Common Name(s): Vertebral body replacement

Classification Name(s): Spinal vertebral body replacement device

2. *Establishment Name & Registration Number:*

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

3. *Classification(s):*

Sec. § 888.3060

Device Class: Class II
Classification Panel: Orthopaedic and Rehabilitation Devices Panel
Product Code(s): MQP

4. *Equivalent Predicate Device:*

coLigne AG. believes that the ***OstaPek® VBR*** is substantially equivalent to the VBR systems identified below:

K052384 – Lanx VBR, Lanx, LLC
K052746 – Concord VBR, DePuy Spine, Inc.
K032064 – Theken LPOD, VBR, Theken, Surgical

Equivalence can be seen in the design, material composition, surgical technique and intended use.

5. *Device Description:*

The implants consist of a system of flattened, cuboid, trapezoida & rectangular shaped implants. The ***OstaPek® VBR System*** implants offer substantial variation of size and configuration to better approximate the anatomical variation observed in different vertebral levels and patient anatomy. The devices are manufactured with one or more hollowed out central areas to accommodate bone graft material. The superior and inferior surfaces are manufactured in such a way that a series of lands and grooves are formed in the anterior/posterior direction. The purpose of these lands and grooves is to improve stability and bony fixation once the device is inserted. This device is made from the exact same material as the ***GII Spinal Fixation System, K051089.***

Testing Summary. Fatigue, static and biocompatibility testing is complete. Samples were tested according to accepted engineering and scientific principals. Test results demonstrate that the new implants may be expected to perform in a manner equivalent or superior to the referenced comparison systems.

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Indications for Use.
The ***OstaPek® VBR System*** are vertebral body (partial or total) replacement devices intended for use in the thoracolumbar spine (T1 - L5) to replace and restore height to a collapsed, damaged, or unstable vertebral body or portion thereof, due to tumor or trauma (fracture or disease). The system is to be used in association with bone graft and supplemental spinal fixation. The supplemental fixation system that is intended is the coLigne, AG, ***GII Spinal Fixation System.***

6. *Applicant Name & Address:*

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

7. *Company Contact:*

Robert Lange
coLigne AG
Utoquai 43
Zurich, Switzerland 8008
41-433-438000
41-433-438009 – fax

8. *Submission Correspondent:*

Mr. David W. Schlerf
Buckman Company, Inc.
1070 Concord Avenue, Suite 230
Concord, CA 94520-5646
925.768.0247 - 925.356.2654 – fax
schlerf@comcast.net or david@fda-help.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

coLigne AG
% Buckman Company, Inc.
Mr. David Schlerf
1070 Conrad Avenue, Suite 230
Concord, CA 94520

JUN 24 2008

Re: K072326
Trade/Device Name: OstaPek® VBR System
Regulation Number: 21 CFR 888.3060
Regulation Names: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: May 14, 2008
Received: June 18, 2008

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.

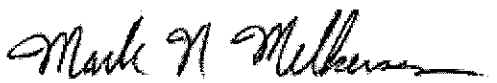
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

510(k) Number: K072326

Device Name(s): *OstaPek® VBR System*

Indications For Use:

The ***OstaPek® VBR System*** are vertebral body (partial or total) replacement devices intended for use in the thoracolumbar spine (T1 - L5) to replace and restore height to a collapsed, damaged, or unstable vertebral body or portion thereof, due to tumor or trauma (fracture or disease). The system is to be used in association with bone graft and supplemental spinal fixation. The supplemental fixation system that is intended is the coLigne, AG, ***GII Spinal Fixation System.***

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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

(Per 21 CFR 801.109) **510(k) Number** K072326 (Optional format 1-2-96)