K032604 p 1/2

510(k) SUMMARY

SUBMITTER NAME: Co-Ligne AG
Utoquai 43
8008 Zurich
Switzerland

510(k) CONTACT: Ariel R. Dujovne, Ing., M.Sc.
Phone: (514) 322-8560 ext 241

TRADE NAME: GII Spinal Fixation System

COMMON NAME: Spinal Fixation System

CLASSIFICATION: 21 CFR §888.3050 and 3070, Spondilolisthesis Spinal Fixation Device System (class II); and Pedicle Screw Spinal system (class II and III)

PRODUCT CODE: MNH/MNI/KWP

PANEL: Orthopedic Devices

PREDICATE DEVICES: GII Spinal Fixation System (K980852), Isola Spinal System (K980485) and Monarch (K010576).

DEVICE DESCRIPTION: The **GII Spinal Fixation System** implants are intended to be used as temporary construct that assists normal healing and are not intended to replace normal body structures.

They are intended to stabilize the spinal operative site during fusion procedures, attaching longitudinal member to the spine by means of spinal anchors. The GII Spinal System is both a rod-based sytems and a plate-based system designed on the same pedicular screw foundation.

The longitudinal members consist of spinal rods or plates. The spinal anchors consist of pedicular screws. Transverse connectors are also included in the system to provide rigidity to the construct. Optional construct spacers are available to allow better seating of the plates or connectors onto the pedicular screws as well as poliaxiality.

INTENDED USE: When used as a pedicle screw fixation system in the non-cervical posterior spine in skeletally mature patients, the GII Spinal System is indicated for one or more of the following: (1) degenerative disc disease (defined as back pain of discogenic origin with

degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, (5) scoliosis, (6) kyphosis, (7) spinal tumor, and/or (8) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the GII@ Spinal System is indicated for skeletally mature patients: (1) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S 1) joint; (2) who are receiving fusions using autogenous bone graft only; (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

The GII Spinal system is also a hook and sacral/iliac screw fixation system of the non-cervical spine indicated for (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, (5) scoliosis, (6) kyphosis, (7) spinal tumor, and/or (8) failed previous fusion (pseudarthrosis).

PERFORMANCE CHARACTERISTICS: Static and Fatigue tests results were supplied to substantiate significant equivalence with previously cleared components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 0 2004

Co-Ligne, AG
c/o Mr. Ariel R. Dujovne, Ing., M.Sc.
Pega Medical Inc.
9260 Viau Boulevard
Montreal, Quebec
H1R 2V8 Canada

Re: K032604
Trade/Device Name: GII Spinal Fixation System
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3050
Regulation Name: Pedicle screw spinal system, Spinal interlaminal fixation orthosis
Regulatory Class: III
Product Code: MNH, MNI, KWP
Dated: December 4, 2003
Received: December 8, 2003

Dear Mr. Dujovne:

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 Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(K) Number: K032604

Device Name: GII Spinal Fixation System

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

for Mark N. Milhous

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

510(k) Number K032604

(Optional Format 1-2-96)