

K973098

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HHL CONSULTING

OCT 27 1997



510(k) Summary of Safety and Effectiveness Information
(as required by 807.92c), prepared by Hartmut Loch, President of
HHL Consulting for PLUS Orthopedics in San Diego, California
October 22, 1997

Trade name: Compression Cerclage Gundolf CCG-GF

Common name: Bone Cerclage

Classification name: Bone Fixation Cerclage

Description: The Compression Cerclage Gundolf CCG-GF is manufactured from commercially pure wrought titanium according to ISO 5832-2 and ASTM F-67. It is 270 mm long, 7.7 mm wide and 0.5 mm thick. It has a fastener at the end that allows the band to encircle the bone and attach itself in a belt-like manner. By using a special manual, tightening instrument the band can impart compression to the bone. The remaining end of the band is cut off using a wire cutter. It has 2 conical shaped 2.9 mm spikes, which are intended to prevent the cerclage band from slipping and give it more stability during the osteointegration period.

Indications: The Compression Cerclage Gundolf CCG is suitable for particular forms of osteosynthesis, particularly for cerclage of the greater trochanter and femur associated with revision hip arthroplasties. In contrast to cerclage wires, the CCG compression band allows a functional compression to be achieved. An assumption is made that an indication for implant revision already exists.

- Reattachment of the greater trochanter.
- Bone support in case of a damaged proximal femur (e.g. by bone cement, loosened stem, or polyethylene wear particles), with a possible cancellous bone graft in the proximal femur area.
- Cerclage of bone fissures.
- Fracture protection during rasping of a new prosthetic canal and prior to implantation of a new stem.
- Closing of a cortical fenestration.
- Fractures in the area of the femoral stem.
- To improve bone-cement interface.

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K973098

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**510(k) Summary of Safety and Effectiveness Information
Compression Cerclage Gundolf CCG-GF
(continued)**

In general, CCG and CCG-GF have the same function. In the case of conical shape of the bone, primarily superior to the lesser trochanter, the CCG-GF is indicated rather than the CCG."

Comparable Features to Predicate Device: The Compression Cerclage Gundolf CCG-GF is identical in design, material, strength, indications and contra-indications to the CCG Cerclage System, which is being sold by Encore Orthopedics, Inc. in Austin, TX (K-932024). In fact, the same company manufactures both cerclage systems: PLUS Endoprothetik AG, Rotkreuz, Switzerland. The modified version in this 510(k) Premarket Notification has the addition of 2 conical shaped 2.9 mm spikes, which are intended to prevent the cerclage band from slipping and give it more stability during the osteointegration period.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Hartmut Loch
President
HHL Consulting
Representing PLUS Orthopedics
835 Cortez Lane
Foster City, California 94404

OCT 27 1997

Re: K973098
Trade Name: Compression Cerclage Gundolf CCG-GF
Regulatory Class: II
Product Code: JDQ
Dated: August 18, 1997
Received: August 19, 1997

Dear Mr. Loch:

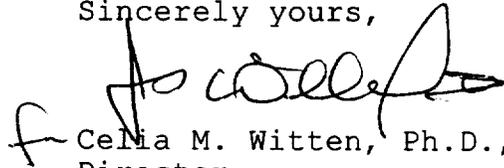
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

Enclosure

510(k) Number (if known): K973098

Device Name: Compression Cerclage Gundolf CCG-GF

Indications for Use:

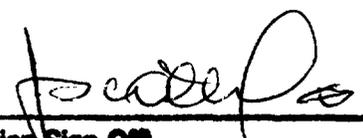
The Compression Cerclage Gundolf CCG is suitable for particular forms of osteosynthesis, particularly for cerclage of the greater trochanter and femur associated with revision hip arthroplasties. In contrast to cerclage wires, the CCG compression band allows a functional compression to be achieved. An assumption is made that an indication for implant revision already exists.

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(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 General Restorative Devices
 510(k) Number K973098

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____