3/15/99

Ponmed Limited

Confidential	Filename Tigran 510(k)	File No. P981112	Date of current draft 2/26/99

Section 16.0 510(k) Summary K984492

510K(k) SUMMARY

SUBMITTER: **Ponmed Limited**

DATE PREPARED: **November 17th, 1998**

DEVICE NAME: **Tigran™ Hip Prosthesis**

CLASSIFICATION NAME: **Femoral Hip Prosthesis**

PREDICATE DEVICES:

The Tigran ™ Hip Prosthesis is substantially equivalent to the Zimmer Versys Hip System (510(k) Number K 964769) and the DePuy Stability™ Hip System (K 915594).

Device Description:

The Tigran™ Femoral Prosthesis for hip arthroplasty consists of three basic parts: femoral heads, femoral stems, and the instrumentation necessary for proper implantation of these components. The femoral stem is made from Titanium Ti-6Al-4V Alloy, a high fatigue strength material with a long history of clinical use and exceptional biocompatibility. The surface of the femoral stem is prepared with a surface finish and pattern to provide optimal initial and lasting fixation in bone. The femoral stem has a collar and is modular in design, incorporating a Morse-type tapered neck and utilizing modular femoral heads. The Femoral stem is straight and with a rectangular cross-sectional shape to provide optimal, rotational stability. The Tigran™ Prosthesis Femoral Stem is available in four neck sizes (short, medium, long and extra long).

The femoral head is fabricated from Cobalt-Chromium-Molybdenum Alloy and comes in three neck configurations (short, medium and long) and in one head diameter (28mm). The various neck lengths provided allow this prosthesis to fit different variations found in the human femora.

The titanium and chrome-cobalt alloy components can be used together, although they are made from dissimilar alloys. In vitro electrochemical corrosion studies have shown that no detrimental changes occur when the two alloys are coupled.

Special instruments are available to assist in mating, disassembling, and the accurate

installation of the implant components.

The Tigran™ Femoral Prosthesis (femoral stem and head) may be used with any acetabular prosthesis with an articulating surface made of ultra high molecular weight polyethylene (UHMWP) and designed to be used with a 28 mm CoCrMo Alloy femoral head.

Intended Use:

The Tigran ™ Hip Prosthesis for total hip arthoplasty consists of three basic parts: femoral heads, femoral stems, and the instrumentation necessary for proper implantation of these components. The Tigran ™ Hip Prosthesis is designed for implantation into the human femur in total or hip replacement and is indicated for the following:

1) Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur
2) Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis;
3) Patients suffering from disability due to previous fusion;
4) Patients with previously failed endoprostheses and/or total hip components in the affected extremity;
5) Patients with acute femoral neck fractures.

This indication statement is essentially the same as the indication statement for the predicate device.

Comparison to Predicate Devices:

All hip systems listed in the previous table are substantially equivalent to each other and to the Tigran ™ Hip Prosthesis which are intended for cementless fixation into the intramedullary canal for pathological or degenerative conditions involving the femur and / or acetabulum. All predicate devices feature a porous or roughened surface and are modular in design. All incorporate pure titanium, a Titanium alloy, or hydroxy apetitie as a surface texture coating or interface for the femoral stem. Each has Morse-type proximal neck taper that mates with a femoral head which, in turn articulates upon the acetabular component. All predicate devices and the Tigran ™ Hip Prosthesis are manufactured from metal alloys that have a history of successful clinical use in orthopedic applications.

The Tigran ™ Hip Prosthesis is substantially equivalent to the Zimmer Versys Hip System (510(k) Number K 964769) and the DePuy Stability™ Hip System (K 915594).

Examination of the information pertaining to the Tigran ™ Hip Prosthesis demonstrates that this device is substantially equivalent in composition, intended use, packaging and labeling to other hip prostheses currently approved for commercial distribution in the United States by the FDA. There are no significant differences between these marketed products and our proposed device.

Summary of Non-Clinical Tests:

Non-clinical mechanical testing was performed to demonstrate that the femoral stem met or exceed the appropriate testing standards / requirements

Clinical Test Results:

Long-term clinical testing was performed and reported on to demonstrate the safety and performance of the Tigran™ Hip Prosthesis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 1999

Jeffrey R. Shideman, Ph.D.
Ponmed Limited
7307 Glouchester Drive
Edina, Minnesota 55435

Re: K984492
Trade Name: Tigran™ Hip Prosthesis
Regulatory Class: II
Product Codes: LPH and JDI
Dated: November 17, 1998
Received: December 17, 1998

Dear Dr. Shideman:

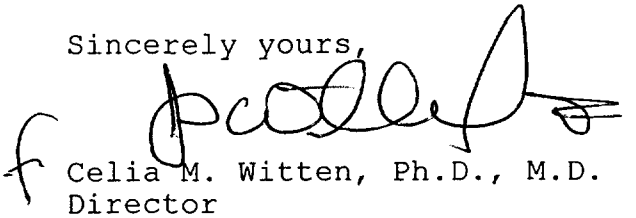
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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*): *K984492*

DEVICE NAME: Tigran Hip Prosthesis

INDICATIONS FOR USE:

Indications for Use Statement

1) Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur
2). Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis;
3) Patients suffering from disability due to previous fusion;
4) Patients with previously failed endoprostheses and/or total hip components in the affected extremity;
5) Patients with acute femoral neck fractures.

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

Concurrence of CDRH, Office of Device Evaluation (**ODE**)

Prescription Use 1 21b
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use N/O
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984492