INTENDED USE

The Renovis T 710 Large External Fixation System is indicated for the following:

- Stabilization/fixation of:
  - Long bone fractures in tibia and femur
  - Fractures of pelvis and ankle
  - Peri-articular and intra-articular fractures of knee and ankle
- Joint arthrodesis
- Non-unions and mal-unions
- Osteotomies

DEVICE DESCRIPTION

The Renovis T 710 Large External Fixation System is an external fixation device consisting of bone pins, connecting rods, clamps, posts and related accessories used for the management of bone fractures and reconstructive orthopedic surgery. The device is a modular system designed to provide a broad range of frame construction options. The connecting rods are made from unidirectional carbon fiber reinforced epoxy. Pins and clamp components are made from materials conforming to ASTM F136 and ASTM F138.

EQUIVALENCE TO MARKETED DEVICE

The Renovis T 710 Large External Fixation System is substantially equivalent in indications and design principles to the following predicate devices each of which has been determined by FDA to be substantially equivalent to pre-amendment devices:

Howmedica Hoffmann Fixation Pin System from Howmedica Corp. (now Stryker Corporation), K861766;

Apex Fixation Pins from Howmedica Osteonics Corp. (now Stryker Corporation), K011136;

Hoffmann II External Fixation System from Howmedica Corp. (now Stryker Corporation), K952730;

Synthes Adjustable Large Fixator System from Synthes (USA), K010344; and

TransFx External Fixation System from Immedica, Inc. (now Zimmer, Inc.), K984357.

The intended use, design principles, materials and overall dimensions of the subject and predicate devices are substantially the same. Both the subject and predicate devices are intended to stabilize traumatic or surgically created instabilities of the pelvis and lower extremities through the use of implantable pins and external components in a variety of sizes. These components are used to create a rigid construct (frame) suitable to the individual needs of the patient. As with one or more of the predicate devices, the implantable bone pins are made from titanium alloy or stainless steel and are distally threaded or centrally threaded to enable unilateral or bilateral frame construction.

p. 1 of 2

Any differences in the technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy.

Data are provided to demonstrate substantial equivalence including detailed engineering analysis of the subject and predicate designs.

Overall, Renovis T 710 Large External Fixation System has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Renovis Surgical Technologies, LLC
% Paxmed International, LLC
David Collette, M.D.
11234 El Camino Real, Suite 200
San Diego, California 92130

MAY 1 1 2011

Re: K110965
Trade/Device Name: Renovis T 710 Large External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: April 6, 2011
Received: April 6, 2011

Dear Dr. Collette:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number: K110965

Device Name: Renovis T 710 Large External Fixation System

Indications for Use:

The Renovis T 710 Large External Fixation System is indicated for the following:

- Stabilization/fixation of:
  - Long bone fractures in tibia and femur
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- Joint arthrodesis
- Non-unions and mal-unions
- Osteotomies

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M Melkerson

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

510(k) Number K110965