AUG 17 2004

K041393

page 1 of 2

Pega Medical

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Montreal, May 24, 2004

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

Contact Person: Ariel R. Dujovne, M.Sc
Pega Medical Inc.
9260 boul Viau, Montreal
Quebec, H1R 2V8 CANADA
(514) 322-8560 ext. 241

Proprietary Name: Fassier-Duval Pediatric IM System

Common Name: Telescopic Nail

Device Classification: Class II

Classification Name: Intramedullary fixation rod
– 21CFR 888.3020/888.3030/888.3040

Establishment Registration Number: 9048931

Intended Use: This implant is indicated as a temporary implant to aid in the healing of long diaphysis fractures, osteotomies, malunions and nonunions and to prevent further fractures in femur, tibia and humerus in pediatric patients suffering from Osteogenesis Imperfecta without disrupting the bone growth plate. It can be used in procedures such as bone lengthening/shortening concomitantly with external fixators in pediatric or small statured patients with limb length discrepancy.

Description: The Fassier-Duval Pediatric IM System is a telescopic rod for use in fixation of long bone fractures. The design of the nail includes a female component (which is attached to the proximal -trochanteric- cortex of the bone) and a male component (which is attached to the distal cortex of the bone). Anchorage of the components is achieved through screw-type fixation or a locking pin. The nail is composed of two sliding components that allow for extension of its length as the bone structures heal and normal patient growth occurs. The Fassier-Duval Pediatric IM System can be attached to bony structures without disrupting the bone growth plates.

Basis for substantial equivalent: The Fassier-Duval Pediatric IM System is claimed to be substantially equivalent in design and function to itself as predicate device:

The intended uses remained unchanged from the original Fassier-Duval Pediatric IM System (K020885) to the modified device, subject of this application.

Design changes have been validated via in-vitro biomechanical testing where deemed necessary. Addition of larges sizes do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2004

Mr. Ariel R. Dujovne, M.Sc
President
Pega Medical, Inc.
9260 boul. Viau, Montreal
Quebec, H1R 2V8 Canada

Re: K041393
Trade/Device Name: Fassier-Duval Pediatric Intramedullary Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: May 24, 2004
Received: June 1, 2004

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.

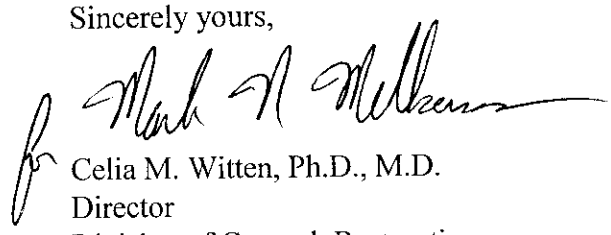
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4659. 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,



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 (if known): K041393
Device Name: Fassier-Duval Pediatric IM system
Indications For Use:

This implant is indicated as a temporary implant to aid in the healing of long diaphysis fractures, osteotomies, malunions and nonunions and to prevent further fractures in femur, tibia and humerus in pediatric patients suffering from Osteogenesis Imperfecta without disrupting the bone growth plate. It can be used in procedures such as bone lengthening/shortening concomitantly with external fixators in pediatric or small stature patients with limb length discrepancy.

Prescription Use _X__ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (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)

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

510(k) Number K041393