APR 16 2014

Premarket Notification [510(k)] Summary

SUBMITTER INFORMATION

Manufacturer's Name:	Pan Medical Ltd
Manufacturer's Address:	Barnett Way, Barnwood, Gloucester, GL4 3RT UK
Telephone (DDI):	+44 1452 621621
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Establishment Registration:	3005146147
Contact Person:	Jennie Budding (Director of R&D/Production)
Date Prepared:	16-April-2014

DEVICE INFORMATION

Trade Name:	InterV Kyphoplasty Catheter
Common Name:	Inflatable Bone Tamp
Device Class:	II
Classification Name:	Polymethylmethacrylate (PMMA) Bone Cement Arthroscope
Classification Panel:	Orthopedic Devices
Classification Regulation:	21 CFR 888.3027 21 CFR 888.1100
Product Code(s):	NDN HRX
Predicate Device:	Kyphon Inflatable Bone Tamp, K981251 Kyphx® Xpander Inflatable Bone Tamps, K041454
Reason for 510(k) submission:	New Device

Device Description: InterV Kyphoplasty Catheter is designed for use in balloon kyphoplasty; it comes as a single-use double lumen catheter with a low profile balloon mounted on the distal tip. The balloon is designed to compress cancellous bone and/or move cortical bone as it inflates. The balloon is designed to withstand bone resistance leading to an internal pressure of up to 400 psi (27 ATM). The key components are the balloon, shaft, Y-connector and two radiopaque marker bands positioned on the inner tubing/lumen at the proximal and distal ends of the inflatable component

Intended use: InterV Kyphoplasty Catheter is intended to be used for reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine during balloon kyphoplasty (for use with cleared spinal polymethymethacrylate (PMMA) bone cements).

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES

Characteristic	New device	Predicate Device
Trade name	InterV Kyphoplasty catheter	Kyphon Inflatable Bone Tamp, K981251 Kyphx® Xpander Inflatable Bone Tamps, K041454
Compatible Cannula Size	8 G / 4.2 mm	8 G / 4.2 mm
Balloon Inflation Medium	60% Contrast	60% Contrast
Balloon Material	Polyurethane	Polyurethane
Balloon Size (Deflated Length)	10, 15 and 20 mm	10, 15 and 20 mm
Guide wire (Stylet)	Stainless Steel	Stainless Steel
Balloon Shape	Cylindrical	Cylindrical
Maximum Recommended Inflation Pressure	400 psi (27 ATM)	400 psi (27 ATM)
Maximum Recommended Inflation Volume (10 mm and 15 mm)	4 ml	4 ml
Maximum Recommended Inflation Volume (20 mm)	6 ml	6 ml

SUMMARY OF NON-CLINICAL TESTS

Characteristic	Test Method	Results Summary
Inflation pressure	Constrained Burst Test	The balloon catheter exceeded the requirements for the minimum burst pressure in a constrained environment
Inflation Volume	Unconstrained Burst Test	The balloon catheter exceeded the requirements for the minimum burst volume in a constrained environment
Inflated Balloon Dimensions	Balloon Inflation Test	The inflated balloon dimensions were substantially equivalent to those of the predicate devices
Balloon Double Wall Thickness	Calibrated Measurement	The double wall thickness of the balloons was substantially equivalent to those of the predicate devices

SUMMARY OF CLINICAL TESTS

N/A- No clinical tests were conducted for this submission

CONCLUSION DRAWN FROM NON-CLINICAL DATA

The results of the non-clinical tests show that the InterV Kyphoplasty Catheter meets or exceeds all performance requirements, and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 16, 2014

Pan Medical Ltd.
Ms. Jennie Budding
Director of R&D/Production
Barnett Way, Barnwood
Gloucester
GL4 3RT
United Kingdom

Re: K132620
Trade/Device Name: InterV Kyphoplasty Catheter
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: February 28, 2014
Received: March 4, 2014

Dear Ms. Budding:

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 contact 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. 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 Industry and Consumer Education 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,

Lori A. Wiggins

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

Enclosure

Indications for Use

510(k) Number (if known): K132620

Device Name: InterV Kyphoplasty Catheter

Indications for Use:

InterV Kyphoplasty Catheter is intended to be used for reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine during balloon kyphoplasty (for use with cleared spinal polymethymethacrylate (PMMA) bone cements).

Prescription Use __X__ AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132620