DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 23, 2017

G-21 S.R.L.
% Mr. Paul Speidel
Senior Regulatory/Quality Consultant
RQMIS, Inc.
110 Haverhill Road
Suite 526
Amesbury, Massachusetts 01913

Re: K172214
Trade/Device Name: Modified Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: July 21, 2017
Received: July 24, 2017

Dear Mr. Speidel:

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 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark N. Melkerson -S

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): K172214

Device Name: **Modified Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters**

Indications for Use:

The Modified Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters are intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. This system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements for use during percutaneous vertebral augmentation, such as kyphoplasty.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

G-21 S.R.L.'s Modified Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters

Submitter G-21 S.R.L.
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Phone: 978-358-7307

Date Prepared: July 21, 2017

Name of Device Modified Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters

Name/Address of Sponsor: G-21
Maurizio Foroni
Via S. Pertini, 8
San Possidonio, Italy 41039

Common or Usual Name

Kyphoplasty Balloon Catheter

Classification Name

Cement, Bone, Vertebroplasty, Class II (21 CFR 888.3027)
Arthroscope, Class II (21 CFR, Sec. 888.1100)

Product Codes

HRX and NDN

Predicate Device

K152557, Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters

Intended Use / Indications for Use

Indications for Use:

> The Modified Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters are intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. This system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements for use during percutaneous vertebral augmentation, such as kyphoplasty.

Technological Characteristics

The Modified Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters are primarily composed of polyurethane, polycarbonate, and polyether/polyamide materials. A Silicone lubricant is provided to facilitate insertion of the catheters. This premarket submission represents a change to the balloon material to a different type of polyurethane.

Device Description

The inflation of the balloon serves to create a cavity in the vertebral body, compressing the cancellous bone and/or move cortical bone, thereby reducing the fracture and preventing cement leakage, while still allowing for cement interdigitation.

Modified Winch Kypholplasy (15 and 20 mm) 11 Gauge balloon catheters fit through a 10 Gauge cannula allowing a minimally invasive kyhoplasty procedure. The low pre-inflation profile (low wrapping profile of folded balloon) enables their insertion into these small working cannulas.

Figure 1: Modified Winch Kyphoplasty 11 Gauge Balloon Catheter

Figure 2: Isometric View of the Modified Winch Kyphoplasty 11 Gauge Balloon Catheter

The stiff distal end of the balloon catheter provides rigidity for smooth insertion while the flexible proximal catheter allows for easy maneuverability. The inflating component, laser-bonded to the shaft, is a low-pressure elastomeric balloon of tubular shape (which is inflated by volume, not pressure). The inflation can expand the balloon several times its original size, it can be inflated to precise dimensions and retain well defined shapes and high pressures and when the pressure is released, it recovers close to its original size and shape, re-folding back to similar original profiles.

Performance Data

Using design FMECA, G21 identified the necessary verification and validation testing to assure the new balloon met the catheters original performance specifications. All testing demonstrated that the modified catheters continues to meet all performance specifications.

Substantial Equivalence

G-21 used dFMECA to determine substantial equivalence. The Modified Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters and the K152557 predicate device have the same intended use/indications for use, equivalent technical characteristics, and identical principles of operation.

G-21 submits the information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the Modified Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters is substantially equivalent in indications, design principles, and performance standards to the predicate device.