October 30, 2023

Biopsybell s.r.l.
℅ Maurizio Pantaleoni
Senior Consultant
Maytal Doo
Kneza Milosa, 79
Belgrade, Serbia 11000

Re: K231340
Trade/Device Name: Renova Spine Balloon Catheter
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: September 29, 2023
Received: September 29, 2023

Dear Maurizio Pantaleoni:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2023.10.30 13:39:55 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHTC: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231340

Device Name
RENOVA SPINE BALLOON CATHETER

Indications for Use *(Describe)*
RENOVA SPINE BALLOON 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 polymethylmethacrylate (PMMA) bone cements).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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1. General Information

Submitter :

Biopsybell srl is located at:
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Establishment Registration Number: 9617616

Contact:

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Summary Preparation Date: April 24th, 2023

2. Name & Classification

Device Name:	RENOVA SPINE BALLOON CATHETER
Regulation Name:	PMMA bone cement
Regulation Number:	888.3027
Product Code:	NDN, HRX
CLASS:	II

3. Predicate Devices

The RENOVA SPINE BALLOON CATHETER is substantially equivalent to the following device:

Applicant	Device name	510(k) Number
PAN MEDICAL LTD	InterV Kyphoplasty Catheter and InterV Kyphoplasty Catheter (Mini)	K150322

4. Indications for Use

RENOVA SPINE BALLOON 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).

5. Device Description

The RENOVA SPINE BALLOON CATHETER is a single use disposable sterile device available in 3 different models depending on the dimensions of the balloon: 10 mm, 15 mm and 20 mm.

RENOVA SPINE BALLOON CATHETER is a single use catheter (double lumen tube) with a balloon at the distal end.

The balloon catheter is normally inserted through a needle / working cannula and inflated through an inflation device.

The catheter has two separate lumens connected to a Y connector at the proximal end of the catheter. The outer lumen of the catheter is used to inflate the balloon while the central lumen contains a removable stylet used to aid in the introduction of the balloon catheter.

6. Comparison with the predicate devices

	Subject device	**Predicate device (K150322)**
Device	RENOVA SPINE BALLOON CATHETER	InterV Kyphoplasty Catheter and InterV Kyphoplasty Catheter (Mini)
510(K) number	-	**(**K150322**)**
Applicant	BIOPSYBELL S.R.L.	PAN MEDICAL LTD.
Classification		
Reg. Number	888.3027 PMMA bone cement	888.3027 PMMA bone cement 888.1100 Arthroscope
Product Code	NDN HRX	NDN HRX
Regulatory Class	II	II
Intended use		
Intended use	RENOVA SPINE BALLOON 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).	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).

	Subject device	Predicate device (K150322)
Mechanism of Action / Mode of Action	The balloon is designed to compress cancellous bone and/or move cortical bone as it inflates The balloon catheter is normally inserted through a needle. Once in place, a hydraulic expansion is performed (ie the balloon is filled with liquid). After removing the balloon the space created is filled with bone cement.	The balloon is designed to compress cancellous bone and/or move cortical bone as it inflates
Design Features		
Single Use Device	YES	YES
Configuration of device	Double lumen catheter with a removable stylet and a balloon at the distal end and an Y connector at the proximal end.	InterV Kyphoplasty Catheter come as a single-use double lumen catheter with a low profile balloon mounted on the distal tip.
Dimensions (Balloon length - deflated)	10 mm 15 mm 20 mm	10 mm 15 mm 20 mm
Compatible Cannula Size	Cannula with diameter: 3,1 mm	Cannula with diameter: 3 mm
Performances (Max inflation pressure)	27 ATM (400 psi)	50 ATM (750 psi)
Materials		
Balloon	Polyurethane	Polyurethane
Catheter	Polyurethane	Polyurethane
Stylet	AISI 304 stainless steel	Stainless steel
Biocompatibility		
Standard	Compliant to ISO 10993-1:	Not known
Sterilization Shelf life		
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Shelf life	3 years	3 years
Performance test for determination of the SE		
Performance tests	Performance tests have been performed on the device, in comparison with predicate device	Performance tests have been performed on the device, in comparison with predicate device

7. Performance Data

A program of design verification and validation testing was performed that includes the following:

- Biocompatibility
- Packaging shelf life accelerated aging tests
- Performance/Functionality/Safety
- EO Sterilization Validation

In particular, performance mechanical tests included:

- Balloon Deflation Time
- Burst Pressure
- Fatigue Strength
- Unconstrained Burst Strength
- Inflated Dimensions
- Tensile Bond Strength
- Insertion and Withdrawal Force

Results of the evaluations demonstrate that the subject device met the safety and performance requirements as per its indication for use.

8. Clinical data

N/A

9. Conclusions

In light of evidences summarized above and based on classification, intended use, technological characteristics and performance data, the subject device is substantially equivalent to the predicate device.