October 28, 2021

GS Medical Co. Ltd.
% Barry E. Sands
Founder and President
RQMIS, Inc.
110 Haverhill Road, Suite 524
Amesbury, Massachusetts 01913

Re: K211797
Trade/Device Name: TRACKER Plus Kyphoplasty System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: September 23, 2021
Received: September 24, 2021

Dear Barry Sands:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: 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)*

Device Name
TRACKER Plus Kyphoplasty System

Indications for Use *(Describe)*
The TRACKER Plus Kyphoplasty System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine, tibia, radius, and calcaneus. This includes percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

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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510(k) SUMMARY

GS Medical ‘s TRACKER Plus Kyphoplasty System 510k Submission

I. SUBMITTER

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Date Prepared: September 23, 2021

II. DEVICE

Trade/Device Name: TRACKER Plus Kyphoplasty System

Common or Usual Name: Inflatable Bone Tamp

Classification Name: Orthopedics

Regulation Number: 21 CFR 888.3027

Regulatory Class: Class II

Product codes NDN, HRX

III. PREDICATE DEVICES

Device	Predicate	Regulation	Product Code	Manufacturer	510(k) Number
TRACKER Kyphoplasty System	Primary	21 CFR 888.3027	NDN, HRX	GS Medical Co. Ltd.	K192335
11G InterV Kyphoplasty Catheter (Flex)	Secondary	21 CFR 888.3027	NDN, HRX	Pan Medical Ltd.	K162453

IV. DEVICE DESCRIPTION

The TRACKER Plus Kyphoplasty System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine, tibia, radius, and calcaneus. This includes percutaneous vertebral augmentation. This system is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

The TRACKER Plus Kyphoplasty System consists of the balloon catheter, cement dispenser kit, and cement mixing system. The cement dispenser kit and the cement mixing system are intended to be used with the balloon catheter, but are sold separately.

V. SUBSTANTIAL EQUIVALENCE

Technological Comparison

The TRACKER Plus Kyphoplasty System is substantially equivalent to other legally marketed inflatable bone tamps. Specifically, the TRACKER Plus Kyphoplasty System is substantially equivalent to TRACKER Kyphoplasty System. The TRACKER Plus Kyphoplasty System has the same general intended use and indications for use and has only minor differences in technological characteristics and principles of operation as the previously cleared primary predicate TRACKER Kyphoplasty System (K192335). The TRACKER Plus Kyphoplasty System also has the same general intended use, technological characteristics, and principles of operation as the previously cleared secondary predicate 11G InterV Kyphoplasty Catheter (Flex) (K162453).

Performance Comparison

In all instances the device functioned as intended and all results were satisfactory and met all performance specifications. The tests performed were:

- Balloon Deflation
- Burst Pressure
- Fatigue Strength
- Unconstrained Burst Strength
- Inflated Dimension
- Tensile bond strength test
- Insertion and withdrawal force test

Comparison to the Predicate Device

	Subject Device	**Primary Predicate Device**	**Secondary Predicate Device**
Device Name	TRACKER Plus Kyphoplasty System	TRACKER Kyphoplasty System	11G InterV Kyphoplasty Catheter (Flex)
510k Number	-	K192335	K162453
Manufacturer	GS MEDICAL Co., Ltd.	GS MEDICAL Co., Ltd.	Pan Medical Ltd.
Product Code	HRX, NDN	HRX, NDN	HRX, NDN
Common Name	Inflatable Bone Tamp	Inflatable Bone Tamp	Inflatable Bone Tamp

Indication for use	The TRACKER Plus Kyphoplasty System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine, tibia, radius, and calcaneus. This includes percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.	The TRACKER Kyphoplasty System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine, tibia, radius, and calcaneus. This includes percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.	8G InterV Kyphoplasty Catheter, 11G InterV Kyphoplasty Catheter (Mini), 13G InterV Kyphoplasty Catheter (Micro) and 11G InterV Kyphoplasty Catheter (Flex) are 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).
Components	- Bone Catheter - Expander Syringe - Kit (Needle Pipe, Needle Pin, Expander, Cannula, Spacer, Guide Wire, Wire Pin, Cement Pusher, Cement Filler, and Guide wire)	- Bone Catheter - Expander Syringe - Kit (Needle Pipe, Needle Pin, Expander, Cannula, Spacer, Guide Wire, Wire Pin, Cement Pusher, Cement Filler, and Guide wire)	- Balloon Catheter
Balloon Size	10mm, 15mm, 20mm	10mm, 15mm, 20mm	20mm
Bone Tamp Max. Inflation Pressure	350 PSI	350 PSI	400 PSI

Composition of Material	Thermoplastic Polyurethane Platinum Polycarbonate & ABS Stainless Steel & ABS	Thermoplastic Polyurethane Platinum Polycarbonate & ABS Stainless Steel & ABS	Balloon Material: Polyurethan
Guide Wire Material	Stainless Steel, Nitinol	Stainless Steel	Nitinol
Packaging	Pouch, Tyvek Blister Tray, Cardboard Box	Pouch, Tyvek Blister Tray, Cardboard Box	Pouch, Cardboard Box
Sterilization	EO Sterilization	EO Sterilization	EO Sterilization
Biocompatibility	Meets ISO 10993	Meets ISO 10993	Meets ISO 10993

VI. NON-CLINICAL TESTING

The performance test was conducted using Tracker Plus Balloon Catheter to evaluate balloon deflation, burst pressure, fatigue strength, unconstrained burst strength, and inflated dimension as per "ISO 10555-4: Intravascular catheters – Sterile and Single use catheters – Part 4: Balloon dilation catheters."

VII. CONCLUSION

The TRACKER Plus Kyphoplasty System is as safe and effective as the TRACKER Kyphoplasty System (Primary Predicate, K192335) and 11G InterV Kyphoplasty Catheter (Flex) (K162453). The TRACKER Kyphoplasty System has the same intended uses and indications for use and has only minor differences in technological characteristics and principles of operation as the previously cleared primary predicate. The TRACKER Plus Kyphoplasty System also has the same general intended use, technological characteristics, and principles of operation as the previously cleared secondary predicate. The technological differences between the subject device and the predicates do not raise new questions of safety and effectiveness. Performance data demonstrate that the TRACKER Plus Kyphoplasty System is as safe and effective as the primary and secondary predicate. Thus, the TRACKER Kyphoplasty System is substantially equivalent to predicate devices.