GPC Medical Limited
Vikas Narang
Director
GPC Square, M-Block, DDA LSC, Vikas Puri, New Delhi
New Delhi, Delhi 110018
India

February 10, 2022

Re: K203811
Trade/Device Name: GPC Intraheal Intramedullary Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HWC, JDS, HTY, JDW
Dated: January 12, 2022
Received: January 14, 2022

Dear Vikas Narang:

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,

For Jiping Chen, M.D., Ph.D., M.P.H.
Acting Division Director
DHT6A: Division of Joint
Arthroplasty 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203811

Device Name GPC Intraheal Intramedullary Nailing System

Indications for Use *(Describe)*

GPC Intraheal Intramedullary Nailing System are provided non-sterile. GPC Intraheal Intramedullary Nailing System are indicated for treating fractures of various bones as given below:
Multi Angle Femoral Nail: The indications for Use of Multi Angle Femoral Nails are as given below:
- To Stabilize Femoral shaft fractures, Subtrochanteric Fractures, Ipsilateral Neck and Shaft Fracturers, Impending Pathologic Fractures, Nonunions and Malunions.

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

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203811

Device Name GPC Intraheal Intramedullary Nailing System

Indications for Use *(Describe)*

Proximal Hip Stabilizing Nail 3: The indications for Use of Proximal Hip Stabilizing Nail 3 are as given below:

Short Nail Indications: -

- Fixation of stable and unstable intertrochanteric fractures, including but not limited to nonunion, malunion
- and tumor resections

Long Nail Indications: -

- Indications may include fractures resulting from trauma, nonunion, malunion, pathological fractures, impending pathological fractures, tumor resections and revision procedures.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203811

Device Name GPC Intraheal Intramedullary Nailing System

Indications for Use *(Describe)*

Elastic Nails:

The Elastic Nail is indicated for fixation of diaphyseal fractures of the long bones where the medullary canal is narrow or flexibility of the implant is paramount. This includes upper extremity fractures in all patients and lower extremity fractures in paediatric or small statured patients. In paediatric application, the flexibility of the elastic nail allows it to be inserted at a point which avoids disruption of the bone growth plate.

K-Wires:

K-wires are indicated to perform as fixation and stabilization unit of bone fractures or as guide at insertion of implants into the skeletal system

All implants are for single use only.

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)

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Premarket Notification 510(k) Summary as required by Section 807.92

General Company Information as required by 807:92(a)

(a.1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared

Submitter's Name:	GPC Medical Limited.
Address:	Office :GPC Square, M-Block, DDA, LSC, VikasPuri New Delhi, 110018 INDIA. Factory : Plot C-3, Sec B-1, UPSIDC, Trans Delhi Signature City, Loni, Ghaziabad, UP 201102
Contact Person Name:	Mr. Vikas Narang
Title:	Director
Phone Number:	+91-9810638797
Dated:	16-12-2020

This is a bundled submission.

Throughout the submission there is a mention of GPC Intraheal Intramedullary Nailing System that represents the range of products covered under this 510(k) submission.

a.2: The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known

Proprietary Name:

- GPC Intraheal Intramedullary Nailing System.

Common or Usual Name:

- Orthopaedic Bone Nail
- Orthopaedic Bone Screw
- Orthopaedic Bone Wire

Classification Name:

- NAIL,FIXATION,BONE
- SCREWS,FIXATION, BONE
- WIRE, FIXATION, BONE

Product Code: HSB, HWC, JDS, HTY, JDW

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Device Class: II

Review Pane: Orthopaedic

Regulation Number: 21CFR888.3020, 21CFR888.3030 and 21CFR888.3040

Device Details:

GPC Intraheal Intramedullary Nailing System are manufactured in various shapes and sizes. The intramedullary nails are fixed with corresponding sizes of locking bolts and end caps. GPC Intraheal Intramedullary Nailing System are manufactured using stainless steel or titanium materials for surgical implant applications.

The different sizes and model numbers of GPC Intraheal Intramedullary Nailing System are based on the site of application such as fixation or reconstruction of the bones. These intramedullary nails are available in different diameters and lengths to suit the patient anatomy and size of the bones.

GPC Intraheal Intramedullary Nailing System are typically divided into following three categories:

1. Femoral Nails and corresponding locking bolts and end cap for fixation
2. Elastic Nails and corresponding end caps for fixation
3. K wire for fixation

The specific names of the GPC Intraheal Intramedullary Nails are as given below:

Multi Angle Femoral Nail
Proximal Hip Stabilizing Nail 3 (Also called as PHN3)
Elastic Nail
K.Wire

A3) Identification of the Predicate Device:

Following are the predicate device 510(k) with which we are declaring substantial equivalence:

Following is the range of variants covered with their corresponding predicate devices.

S. No.	Subject Device	Predicate Device
01.	Multi Angle Femoral Nail	Synthes Lateral Entry Femoral Nail (K040336)
	Locking Bolts 6.5mm (Self Tapping)	Synthes Lateral Entry Femoral Nail (K040336) (Synthes LFN)
	Locking Bolt 4.9mm, Self Tapping	GPC Tibial Nail System Ex (K143245) and Synthes Trochanteric Fixation Nail (TFN) SYSTEM (K011857)

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02.	Proximal Hip Stabilizing Nail 3 (Short and Long)	Gamma 3 Nail System (K043431)
	Cephalic Screw for Proximal Hip Stabilizing Nail 3	Gamma 3 Nail System (K043431)
	Locking Bolt 5.0mm	Gamma 3 Nail System (K043431)
03.	Elastic Nail Titanium End Cap of Elastic Nail Titanium	Synthes Elastic Intramedullary Nail (EIN) System (K971783) Synthes Elastic Intramedullary Nail (EIN) End Cap K053105
04.	K. Wire	SMT Schilling Metalltechnik GmbH (K100736)

NOTE: The end cap of each type of intramedullary nail is also part of the corresponding intramedullary nail and no separate predicate device is applicable for the end caps.

a4). A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device

Device Description of GPC Intraheal Intramedullary Nailing System:

There are following types of Bone Nails used with Locking Screws and Bolt and Wires. The Bone Nails are generally designed on the basis of the bones.

S. No.	Type	Variants	Angles	Diameters	Lengths	Material of Construction
1.	Multi Angle Femoral Nail	With Left and Right Versions	--	9mm to 12mm	300mm to 460mm	Stainless Steel and Titanium
2.	Proximal Hip Stabilizing Nail 3	Short	120 degree, 125 degree, 130 degree	10mm, 11mm & 12mm	180mm to 220mm	Stainless Steel and Titanium
		Long(with Left and Right Versions)	120 degree, 125 degree, 130 degree	10mm, 11mm & 12mm	300mm to 480mm	Stainless Steel and Titanium
3.	Elastic Nail Titanium	--	--	2.0mm to 4.0mm	440mm	Titanium

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4.	K. Wire Diameter 1.0mm to 4.5mm with length: 100 to 300mm	With Partial Thread, Single Side Trocar, Both Side Trocar	--	1.0-4.5mm	100mm to 300mm	Stainless Steel and Titanium
5.	Locking Bolts 4.9 mm, self-tapping	--	--	4.9mm	26-60mm(2mm increment), (64-80mm) 4 mm increment (80-100mm) 5mm increment	Stainless Steel and Titanium
6.	Self Tapping Locking Bolts 6.5mm	--	--	6.5mm	60mm to 130mm in 5 mm increments	Stainless Steel and Titanium
7.	Locking Bolts 5.0 mm, self-tapping	--	--	5.0mm	26mm to 60mm with 2mm increment and 60 to 120mm with 5 mm increment	Stainless Steel and Titanium
8.	Cephalic Screw	--	--	10.5mm	70mm-130mm with 5mm increments	Stainless Steel and Titanium

These implants are supplied non-sterile, the products have to be sterilized prior to use.

A5).A statement of the intended use of the device

Indications for Use:

GPC Intraheal Intramedullary Nailing System are provided non-sterile.

GPC Intraheal Intramedullary Nailing System are indicated for treating fractures of various bones as given

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below:

Multi Angle Femoral Nail: The indications for Use of Multi Angle Femoral Nails are as given below:

-To Stabilize Femoral shaft fractures, Subtrochanteric Fractures, Ipsilateral Neck and Shaft Fracturers, Impending Pathologic Fractures, Nonunions and Malunions.

Proximal Hip Stabilizing Nail 3: The indications for Use of Proximal Hip Stabilizing Nail 3 are as given below:
Short Nail Indications: -
•Fixation of stable and unstable intertrochanteric fractures, including but not limited to nonunion, malunion and tumor resections
Long Nail Indications:-
•Indications may include fractures resulting from trauma, nonunion, malunion, pathological fractures, impending pathological fractures, tumor resections and revision procedures.

Elastic Nails:
The Elastic Nail is indicated for fixation of diaphyseal fractures of the long bones where the medullary canal is narrow or flexibility of the implant is paramount. This includes upper extremity fractures in all patients and lower extremity fractures in paediatric or small statured patients. In paediatric application, the flexibility of the elastic nail allows it to be inserted at a point which avoids disruption of the bone growth plate.

K-Wires:
K-wires are indicated to perform as fixation and stabilization unit of bone fractures or as guide at insertion of implants into the skeletal system

All implants are for single use only.

a6). Summary of Technological Characteristics as compared to the predicate devices:

Substantial equivalence including comparison with predicate devices

A comparison between the **GPC** Intraheal Intramedullary Nailing System and predicate devices has been performed which has resulted in demonstration of similarities in dimensional and performance criteria.

Following is the summary of parameters in which the comparison has been verified:

S. No.	Characteristics	**Predicate Device Versus New Device (GPC Intraheal Intramedullary Nailing System)**	Remarks on Equivalence
01	Regulatory Classification	**Same Classification and Regulation Number**	Equivalent
02	Indications for use	Similar intended use in New Device and Predicate device	Equivalent

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03	Material	Both the predicate and subject devices use material meant for surgical implant application	Equivalent
04	Performance Standards	Same performance standards used in both New Device as well as predicate device	Equivalent
05	Sterilization	Same method of sterilization used in both New Device as well as Predicate device	Equivalent
06	Dimensional Verification	Similar dimensions found in both New Device as well as Predicate device The minor differences that exist, do not raise any safety concerns.	Equivalent

b1).Discussion on the non-clinical testing performed

Following are the applicable product standards considered for non-clinical standards

A: Material Standards

B: Performance Standards

A: Material Standards:

The material standards are the essential part to be complied to first, as it is the basis of manufacturing metallic surgical implants.

We have complied to following material standards

1. ASTMF136: Standard specification for wrought Titanium-6 Aluminium-4 VanadiumELI (Extra low interstitial) Alloy for surgical implant applications.

2. Stainless Steel 316L and Stainless Steel 316LVM

The purchased material are in compliance to these standards.

B: Performance Standards:

The device performance of **GPC** Intraheal Intramedullary Nailing System has been demonstrated against following applicable standards

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For Intramedullary Nails:

- The testing performed As per ASTMF1264 and ASTM F 384

Static Four Point Bend Test: Conforms

Bending Fatigue Properties: Conforms

Static Torsional Testing: Conforms

Compression Bending: Conforms

For Bone Screws:

- The Testing Performed As per ASTMF 543:
  Torsional Properties: Conforms,
  Driving Torque :Conforms,
  Pull-out Test: Conforms

For Bone Wires:

Tensile Testing as per ASTM F 136 and ASTM F 138: Conforms

b2). Discussion on the clinical evaluation referenced and relied up on:

GPC Intraheal Intramedullary Nailing System are of similar design and pattern as well as similar intended use as that of predicate devices which are in market already and in clinical use. Therefore Clinical information was not necessary to demonstrate substantial equivalence.

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CONCLUSION:

General, Safety and Performance conclusion:

From the available data available we can justify that the **GPC** Intraheal Intramedullary Nailing System are as safe, as effective and perform as same indications for use as that of already marketed predicate devices identified in a 3.of 510(k) summary.

Hence these devices can be considered safe and effective for their intended use.