January 7, 2022

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

Re: K210198
Trade/Device Name: GPC 2.4 mm Variable Angle Locking Two Column Volar Distal Radius Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: December 6, 2021
Received: December 6, 2021

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,

Shumaya Ali, M.P.H.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210198

Device Name GPC Variable Angle Locking Two Column Volar Distal Radius Plating System

Indications for Use *(Describe)*

GPC Variable Angle Locking Two Column Volar Distal Radius Plating System is provided non-sterile.
GPC Variable Angle Locking Two Column Volar Distal Radius Plating System
is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.
The system is indicated for use in adult patients only. All implants are for single use only.

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.

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GPC Medical Ltd

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

Submitter's Name: GPC Medical Ltd.

Address: Office : GPC Square, M-Block, DDA, LSC, Vikas Puri 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: 25-05-2021

Proprietary Name:

- **Name of the Device: GPC Variable Angle Locking Two Column Volar Distal Radius Plating System**

Common or Usual Name:

- Orthopaedic Bone Plates
- Orthopaedic Bone Screws

Classification Name:

- PLATE,FIXATION,BONE
- SCREW,FIXATION, BONE

Product Code: HRS (Primary), HWC

Device Class: II

Review Pane: Orthopaedic

Regulation Number: 21CFR888.3030 (Primary) and 21CFR888.3040

Device Details:

- **GPC Variable Angle Locking Two Column Volar Distal Radius Plates** are manufactured in various shapes and sizes. The GPC Variable Angle Locking Two Column Volar Distal Radius Plates are fixed with corresponding sizes of locking screws.

A3) Identification of the Predicate Device:

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

Primary predicate: Synthes (USA) 2.4mim VA-LCP Two-Column Narrow Volar Distal (K092556)

Additional Predicate: Synthes 2.4mm Variable Angle LCR Volar Rim Distal Radius System (K110125)

Reference Device: Synthes 2.4 mm VA-LCP Two-Column Volar Distal Radius Plate (K083694)

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

GPC Variable Angle Locking Two Column Volar Distal Radius Plates are machined metal plates designed for fixation of various fracture modes of the distal portion of the radius. The Variable Angle Locking Two Column Volar Distal Radius Plates allow fragment-specific fracture fixation by providing the flexibility to lock screws in the head or shaft of the plate in trajectories that can diverge from the central axis of the plate hole. The variable angle locking mechanism improves the plate-screw construct stability. **GPC Variable Angle Locking Two Column Volar Distal Radius Plates** are manufactured using titanium material for surgical implant applications.

Following are the types of the GPC Variable Angle Locking Two Column Volar Distal Radius Plates:

- Variable Angle Locking Two-Column Volar Distal Radius Plate, Width 22 mm, 6 Head Holes (with option of Left and Right Variants)
- Variable Angle Locking Two-Column Volar Distal Radius Plate, Width 25.5 mm, 7 Head Holes (with option of left and right variants)
- Variable Angle Locking Two Column Volar Distal Radius Plate- Narrow, Width 19.5 mm, 6 Head Holes (with option of left and right variants)

Corresponding Screws for fixation:

- Variable Angle Locking Screw 2.4 mm, Star drive Lengths: 6mm to 30mm in 2mm increments
- FixLOCK Self-Tapping Screw 2.4 mm, Star drive Length 6mm to 30mm in 2mm increments
- Self-Tapping Cortex Screw 2.7 mm, Star drive Length: 12mm to 24mm

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

A5). Indications for Use:

GPC Variable Angle Locking Two Column Volar Distal Radius Plating System is provided non-sterile.

GPC Variable Angle Locking Two Column Volar Distal Radius Plating System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones. The system is indicated for use in adult patients only. All implants are for single use only.

A6). Summary of Technological Characteristics as compared to the predicate devices:

A comparison between the **GPC Variable Angle Locking Two Column Volar Distal Radius Plating 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 Variable Angle Locking Two Column Volar Distal Radius Plates)	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
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

The device performance of **GPC Variable Angle Locking Two Column Volar Distal Radius Plating System** has been demonstrated against following applicable standards

For GPC Variable Angle Locking Two Column Volar Distal Radius Plates:

- The testing performed as per ASTMF382

Static Four Point Bend Test: Conforms
Bending Fatigue Properties: Conforms

For Bone Screws:
The Testing Performed As per ASTMF 543:
Torsional Properties: Conforms,

Driving Torque : Conforms,
Pull-out Test: Conforms

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

GPC Variable Angle Locking Two Column Volar Distal Radius Plating System is 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.

CONCLUSION:

From the available data we can justify that the **GPC Variable Angle Locking Two Column Volar Distal Radius Plating System** is 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.