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

May 17, 2016

GPC Medical Limited
Mr. Vikas Narang
Director-Exports
M-Block, DDA LSC, Vikas Puri
New Delhi, 110018
INDIA

Re: K153716
Trade/Device Name: GPC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System
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: April 8, 2016
Received: April 11, 2016

Dear Mr. 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. 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 Parts 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″ (21CFR 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 yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153716

Device Name
GPC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System.

Indications for Use *(Describe)*

GPC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System are indicated for treating fractures of various bones including the clavicle, pelvis, scapula, long bone (humerus, ulna, radius, femur, tibia and fibula), and small bone (metacarpals, metatarsals, phalanges).

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)*

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

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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 Ltd.

Address:

Office:
M Block, DDA LSC, Vikas Puri, New Delhi 110018
India

Factory:
A-82, Sector A-4, Tronica City, Loni, Ghaziabad, Uttar Pradesh

201102

Contact Person Name: Mr. Vikas Narang

Title: Director-Exports

Phone Number: +91-9810638797

Dated: 21-12-2015

This is a bundled submission.

Throughout the submission there is a mention of **GPC BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System that represents the range of products covered under this 510(k) submission.

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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 BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System.

Common or Usual Name:

- Orthopaedic Bone Plates
- Orthopaedic Bone Screws

Classification Name:

- PLATES, FIXATION, BONE
- SCREWS, FIXATION, BONE

Product Code: HRS, HWC

Device Class: II

Review Pane: Orthopaedic

Regulation Number: 21 CFR 888.3030 and 21 CFR 888.3040

Variants/Types: **GPC BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System are further subdivided into following categories

S. No.	Category	Types
01	Large Fragment Plates	Locking Version
02	Small Fragment Plates	Locking Version
03	Mini Fragment Plates	Locking Version
04	Bone Screws	Locking and Non-Locking Version

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Further Description of **GPC BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System.

Generally there are following types of bone plates used with cortical (cortex) and Locking Screws. These bone plates are generally designed on the basis of the bone contour and anatomy.

S. No.	Type	Subtype
01	Small and Large Fragment	T-Shaped, Hook Angled Plates. Reconstructions plates
02	Dynamic compression	Small DCP, Narrow DCP, Lengthening Narrow, Broad DCP, Lengthening Broad Plates
03	Mini Fragment	T-Shaped

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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	**4.5mm Narrow Locking Plate**	Synthes 3.5 and 4.5mm Locking Compression Plate System (K082807)
02	**4.5mm Broad Locking Plate**	Synthes 3.5 and 4.5mm Locking Compression Plate System (K082807)
03	**4.5mm/5.0mm Broad Curved Locking Plate**	Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad Locking Compression Plates (K082807)
04	**4.5mm Reconstruction Locking Plate**	Synthes 4.5 mm LCP Straight Reconstruction Plate (K051986)
05	**Proximal Femur Locking Plate**	Synthes (USA) LCP Proximal Femur Plate (K030858)
06	**Locking Lateral Proximal Tibia Plate, Left and Right**	Synthes LCP Proximal Tibia Plate (K023802, K030597, K983787)
07	**4.5mm Distal Femur Locking Plate, Left and Right**	Synthes LCP Distal Femur Plates (K062564)
08	**Locking T-Plate 3.5mm, Oblique Angled, Left and Right**	Synthes Small Fragment Dynamic Compression Locking(DCL) System (K000684)
09	**Small Dynamic Compression Plate 3.5mm with LC Under Cuts**	Synthes 3.5 (USA) Locking Compression Plate System (K082807)
10	**3.5mm Small 'T' Plate – 3 Head Holes**	Synthes Small Fragment Dynamic Compression Locking(DCL) System(K000684)
11	**3.5mm Small 'T' Plate – 4 Head Holes**	Synthes Small Fragment Dynamic Compression Locking(DCL) System(K000684)
12	**Proximal Tibia Locking Plate, Left and Right**	Synthes 3.5mm Titanium LCP Proximal Tibia Plate (K030597) OR Synthes LCP Proximal Tibia Plates (K011978)

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13	**Locking Anterolateral Tibia Distal Plate 3.5mm**	Synthes (USA) LCP Anterolateral Distal Tibia Plate 3.5 (K092812)
14	**Locking Clavicle Hook Plate 3.5mm, Left and Right**	Synthes Clavicle Hook Plate (K061753)
15	**3.5mm Proximal Humerus Locking Plate**	Proximal humerus plate long Synthes K041860 K062494 EBI Optilock Upper Extremity Plating System
16	**Distal Humerus Locking Plate, Size 2.7/3.5mm, Left and Right**	Synthes 3.5mm LCP Distal Humerus System (K033995)
17	**Distal Humerus Locking Plate, 2.7/3.5mm with Lateral Support, Left and Right**	Synthes 3.5mm LCP Distal Humerus System (K033995)
18	**Locking Medial Distal Tibia Plate without Tab, Left and Right**	Synthes Medial Distal Tibia Plate (K001945)
19	**Locking Philous Plate**	Synthes (USA) LCP® Proximal Humerus Plates, Long (K041860)
20	**'T' Distal Radius 2.4mm Locking Plate**	K982732 or K012114 (Synthes locking distal radius plating system)
21	**Locking Distal Radius Buttress Plate 2.4mm**	Synthes (USA) LCP Radial Head Plating System (K040777)
22	**Self Tapping Locking Screw 2.4mm**	Synthes 2.4mm Titanium locking screw (K033975) K051567 APTUS Titanium Fixation System
23	**Self Tapping Locking Screw 2.7mm**	Synthes Small Fragment Dynamic Compression Locking (DCL) System (K000684) K051567 APTUS Titanium Fixation System
24	**Self Tapping Locking Screw 3.5mm**	Synthes Small Fragment Dynamic Compression Locking (DCL) System (K000684) K051567 APTUS Titanium Fixation System

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25	**Self Tapping Locking Screw 5.0mm**	Synthes Large Fragment Dynamic Compression Locking (DCL) System (K000682) K051567 APTUS Titanium Fixation System
26	**6.5mm Self Tapping Locking Cannulated Screw**	Synthes Cannulated Screw System K021932 K051567 APTUS Titanium Fixation System

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:

GPC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System consists of various shape and sizes of plates featuring compression and locking holes, full-threaded-cortical, locking self-tapping screws.

The plates and screws are fabricated from Stainless Steel and Titanium.

GPC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System contains several models based on the size of the device and application site such as fixation/reconstruction of small fragment bones, forefoot, mid-foot, rear-foot, ankle, or other bones appropriate for the size of the device. The plate implants are in many models available: like, Reconstruction Plates, T-Plates, Anatomical Plates and Clavicle Hook Plates.

These all are mainly divided into

- Large Fragment Plates
- Small Fragment Plates
- Mini Fragment Plates

The number of the holes varies from 2 to 22.

The Locking screw implants are in corresponding diameter ranges from 2.4mm, 2.7mm, 3.5mm, 5.0mm and 6.5mm diameters with lengths varying as per the requirements and minimum length: 20 mm to maximum length 150mm

The Non-locking screw implants are in 3.5mm and 4.5mm diameter and length range from 10mm to 140mm. The non locking screws 3.5mm and 4.5mm were cleared previously in 510k

number K092493

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

K153716

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A5). (5) A statement of the intended use of the device

Indications for Use:

• **GPC BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System are provided non-sterile.

GPC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System are indicated for treating fractures of various bones including the clavicle, pelvis, scapula, long bone (humerus, ulna, radius, femur, tibia and fibula), and small bone (metacarpals, metatarsals, phalanges).

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:

Substantial equivalence including comparison with predicate devices

A comparison between the **GPC BRAND** Locking Bone Plates and Screws Osteosynthesis 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 Brand)	Remarks
01	Indications for use	Similar intended use in New Device and Predicate device	Equivalent
02	Material	Same material used in New Device and Predicate device	Equivalent
03	Performance Standards	Same performance standards used in both New Device as well as predicate device	Equivalent
04	Sterilization	Same method of sterilization used in both New Device as well as Predicate device	Equivalent
05	Dimensional Verification	Same dimensions found in both New Device as well as Predicate device	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. ASTM F 136: Standard specification for wrought Titanium-6Aluminium-4Vanadium ELI (Extra low interstitial) Alloy for surgical implant applications.
2. ASTM F 138: Standard Specification for Wrought 18 chromium-14Nickel-2.5Molybdenum stainless steel bar and wire for surgical implants.
3. ASTM F 139: Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants

We have verified the purchased material compliance to these standards and copies of the relevant test results were provided in the submission.

The performance of the plates was demonstrated using an engineering analysis of bending moment and bending stiffness based on material properties and the plate shaft dimensions.

The performance of the screws was demonstrated using an engineering analysis of pull-out strength and torque-to-failure based on material properties and the screw dimensions.

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

GPC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System are of similar design and pattern as well as similar intended use. Clinical information was not necessary to demonstrate substantial equivalence.

CONCLUSION:

General, Safety and Performance conclusion:

From the available data available we can justify that the **GPC BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System are as safe, as effective and perform as same indications for use as that of already marketed predicate devices identified in a3. of 510(k) summary.

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