DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 31, 2017

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

Re: K163096
Trade/Device Name: GPC Brand Posterior, Non cervical Pedicle Screw Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: February 20, 2017
Received: February 23, 2017

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 Part 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" (21 CFR 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,

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)*
K163096

Device Name
GPC Brand Posterior, Non cervical Pedicle Screw Spinal System

Indications for Use *(Describe)*
The GPC BRAND Posterior, Non cervical Pedicle Screw Spinal System is intended for use in the noncervical spine. The GPC BRAND Posterior, Non cervical Pedicle Screw Spinal System is used as an adjunct to fusion, using autograft or allograft, in the treatment of the following instabilities and deformities in skeletally mature patients.

1. Degenerative Disc Disease (DDD, defined as back pain of discogenic origin with degeneration of disc confirmed by history & radiographic studies)
2. Spondylolisthesis
3. Trauma (Fracture or Dislocation)
4. Spinal Stenosis
5. Scoliosis, kyphosis and/or lordosis
6. Pseudoarthrosis
7. Failed Previous Fusion

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)*

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

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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, Vikas Puri, New Delhi 110018 India

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

201102

ContactPersonName: Mr. Vikas Narang

Title: Director-Exports

Phone Number: +91-9810638797

Dated: March 30, 2017

Throughout the submission, there is a mention of **GPC BRAND Posterior, Non cervical Pedicle Screw Spinal 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

ProprietaryName:

- **GPC BRAND Posterior, Non cervical Pedicle Screw Spinal System**.

ProductCode: NKB

Device Class: II

ReviewPane: Orthopaedic

Regulation Number: 21 CFR 888.3070 Thoracolumbosacral Pedicle Screw System

Variants/Types: GPC BRAND Posterior, Non cervical Pedicle Screw Spinal System are further subdividedintofollowing categories

S.No.	Category	Variants
01	Single Lock Monoaxial Screw (with inner screw)	MAS42 and SPS42
02	Single Lock Polyaxial Screw (with inner screw)	MAS44 and SPS44
03	Transverse Connector	No variants
04	Rod	No variants

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A3) Identification of the Predicate Device:

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

S. No.	Subject Device	Primary Predicate	Additional Predicates
01	**GPC BRAND Posterior, Non cervical Pedicle Screw Spinal System**	Zodiac Polyaxial Spinal Fixation System (K100685)	Scient'X MX Monoaxial Pedicle Screw System (K042964)

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

Device Description:

GPC BRAND Posterior, Non cervical Pedicle Screw Spinal System

The Monoaxial & Polyaxial screw consists of a body, bushing, and ball head screw.
Inner Screw, rods and transverse connectors assemblies complete the spinal construct. The body portion of the screw rotates about the ball head on the screw, which provides increased motion over a fixed post or monoaxial screw. An increase in motion facilitates the capture of rods that are not perfectly aligned.

The Screws, Rods &Transverse Connectors are fabricated from Titanium.

The system contains several models based on the size of the device and application site such as fixation/reconstruction spine.

- Single Lock Monoaxial Screw
- Single Lock Polyaxial Screw
- Transverse connector
- Rod

The diameter of these screw varies from 4mm to 7mm with length 25mm to 50mm.
The corresponding connector are small & large in size.
The diameter of Rod is 5.5mm with length 75mm to 150mm

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

Further Description of **GPC BRAND Posterior, Non cervical Pedicle Screw Spinal System**

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Monoaxial Bone Screw: This screw is used in various spinal fixation situations in conjunction with otherhardware to create a rigid construct. The monoaxial screw consists of a body and ball head screw.

Polyaxial Bone Screw: This screw is used in various spinal fixation situations in conjunction with other hardware to create a rigid construct. The polyaxial screw consists of a body, bushing, and ball head screw.

Inner screw, Rod and transverse connector assemblies complete the spinal construct. The body portion of the screw rotates about the ball head on the screw, which provides increased motion over a fixed post or monoaxial screw. An increase in motion facilitates the capture of rods that are not perfectly aligned. Inner screws are used to secure the bone screw and rod interface

Straight Rods: Rods are used to connect pedicle screws and create a rigid structure.

Transverse Connectors: Connectors are used to connect to rods together to create a more rigid construct.

The diameter of these screw varies from 4mm to 7mm with length 25mm to 50mm.
The corresponding connector are small & large in size.
The diameter of Rod is 5.5mm with length ranging from 75mm to 150mm
The inner screw is of standard size throughout the range of monoaxial and polyaxial screws.

Sizes of the Subject Devices for both Design I & Design II:

Transverse Connector: Design I and Design II

Straight Rod:

5.5mm Dia:75mm, 80mm, 100mm, 125mm, 150mm

Monoaxial screw:

4.5mm Dia: 25mm, 30mm, 35mm, 40mm, 45mm, 50mm

5.5mm Dia: 25mm, 30mm, 35mm, 40mm, 45mm, 50mm

6.0mm Dia: 25mm, 30mm, 35mm, 40mm, 45mm, 50mm

7.0mm Dia: 25mm, 30mm, 35mm, 40mm, 45mm, 50mm

Polyaxial Screws:

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4.5mm Dia: 25mm, 30mm, 35mm, 40mm, 45mm, 50mm

5.5mm Dia: 25mm, 30mm, 35mm, 40mm, 45mm, 50mm

6.0mm Dia: 25mm, 30mm, 35mm, 40mm, 45mm, 50mm

7.0mm Dia: 25mm, 30mm, 35mm, 40mm, 45mm, 50mm

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

Indications for Use:

The GPC BRAND Posterior, Non cervical Pedicle Screw Spinal System is intended for use in the noncervical spine. The GPC BRAND Posterior, Non cervical Pedicle Screw Spinal System is used as an adjunct to fusion, using autograft or allograft, in the treatment of the following instabilities and deformities in skeletally mature patients:

1. Degenerative Disc Disease (DDD, defined as back pain of discogenic origin with degeneration of disc confirmed by history & radiographic studies)
2. Spondylolisthesis
3. Trauma (Fracture or Dislocation)
4. Spinal Stenosis
5. Scoliosis, Kyphosis and/or lordosis
6. Pseudoarthrosis
7. Failed Previous Fusion

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 Posterior, Non cervical Pedicle Screw Spinal System**
And predicate devices has been performed which has resulted in demonstration of similarities in dimensional and performance criteria.

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

S.No.	Characteristics	Predicate Device Versus New Device (GPCBrand)	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. ASTMF136:Standard specification for wrought Titanium-6Aluminium-4Vanadium ELI (Extra low interstitial) Alloy for surgical implant applications.

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B:Performance Standards:

The device performance of **GPC BRAND** Pedicle Screw System has been demonstrated against following applicable standards

1. ASTM F 1717: Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model

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

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

GPC BRAND Posterior, Non cervical Pedicle Screw Spinal 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 Posterior, Non cervical Pedicle Screw Spinal 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 this system can be considered substantially equivalent to the identified predicates.