May 5, 2021

Biorad Medisys PVT LTD
Sudhakar Saxena
General Manager Regulatory Affairs
Survey No 48/3 & 48/7, Pashan Sus Road, Sus Village,
Taluka Mulshi
Pune, Maharashtra 411021
INDIA

Re: K200765
Trade/Device Name: Genius / Genuin Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: March 26, 2021
Received: April 5, 2021

Dear Sudhakar Saxena:

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,

Ting Song, Ph.D., R.A.C.
Assistant 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)*
K200765

Device Name
Genius / Genuin Total Knee System

Indications for Use *(Describe)*

Indicated for use only with bone cement for patients suffering from: Severe knee joint pain, loss of mobility and disability due to: rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, Correction of functional deformities. Post-traumatic loss of knee joint contour, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy; Moderate valgus, Varus or flexion trauma. Knee fractures untreatable by other methods.

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.**

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(K) SUMMARY

**SPONSOR**

| | |
|---|---|
| **Name:** | Biorad Medisys Pvt Ltd. |
| **Address:** | Survey No 48/3 & 48/7, Pashan Sus Road Sus Village, Taluka Mulshi Pune, India. Maharashtra - 411021 |
| **Phone:** | +91 020-30912000 |
| **Fax:** | +91 020-30912050 |
| **Name of Contact Person:** | Sudhakar Saxena |
| **Designation:** | General Manager Regulatory |
| **Date Prepared:** | May 04, 2021 |

**DEVICE**

| | |
|---|---|
| **Name of Device:** | Genius / Genuin Total Knee System |
| **Common Name:** | Total Knee System |
| **Classification Name:** | Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer (21 CFR 888.3560) |
| **Product code:** | JWH |

**PREDICATE DEVICE**

PFC Sigma Knee System (K182301), manufactured by DePuy Orthopaedics, Inc

**510(K) SUMMARY**

**DEVICE DESCRIPTION**

The Genius / Genuin Total Knee System has 3 major components:

- Femoral component
- Tibial component - Includes Tibial Tray and Tibial Insert
- Patellar component

The brief description of each major component is provided below:

**Femoral Component:** Femoral component is a posterior stabilized (PS) design for femoral prosthesis fabricated from CoCrMo Alloy (Cobalt-Chromium-Molybdenum) conforming to ASTM F75 – 18 & ISO 5832-4:2014. It is intended for cemented application to replace the articulating surface of the distal femur. The articulating surface of femoral component interfaces with the Tibial Insert to facilitate flexion-extension and internal-external rotational movement. Femoral component of Genius / Genuin Total Knee System design has both Left and Right configurations. Each of the Left and Right configurations are available in eight different sizes namely A, B, C, D, E, F, G & H where A corresponds to the smallest femoral component and H corresponds to the largest femoral component. The sizes are based on the anterior/posterior (A/P) and medial/lateral (M/L) dimensions.

**The range of motion for the Genius / Genuin Total Knee System** - femoral component is designed to range from 00 to 155° of flexion and provides the I/E rotation up to ±15° in extension and up to ±25° in flexion.

**Tibial Component:** The Tibial component comprises of two parts:

- Tibial tray
- Tibial Insert

**Tibial Tray:** Tibial tray comprises of a tibial platform that securely holds the Tibial Insert with a dovetail locking mechanism, and fabricated from CoCrMo (Cobalt-Chromium-Molybdenum) Alloy conforming to ASTM F75 – 18 & ISO 5832-4:2014. It is intended for cemented application. The bottom of the tibial tray component has a 0.8mm cement pocket depth for optimum fixation of the prosthesis to bone. Tibial tray is available in 6 different sizes namely size 1, 2, 3, 4, 6 & 7 wherein 1 corresponds to the smallest tibial size and 7 corresponds to largest tibial size.

**Tibial Insert:** Tibial insert is configured to have articulating surfaces over one side on which the articulating surface of the femoral component rolls/moves to achieve required flexion-extension and rotational movements. The other side comprises of a dovetail locking (snap-fit) feature that gets securely interlocked with the tibial tray during the surgery. The tibial insert is fabricated from UHMWPE conforming to ASTM F648 – 14 & ISO 5834-2:2019. Tibial insert component is available in 8 sizes and each of the inserts are available with 8 different thicknesses i.e. Thickness-7, 8, 9, 10, 11, 13, 15 and 17mm.

**Patella Component: T**he patella component is a dome shaped prosthesis made of UHMWPE conforming to ASTM F648 – 14 & ISO 5834-2:2019. It has 3 pegs on the opposite side of dome to facilitate better fixation with the resurfaced patellar bone. It is intended for cemented use only. It is designed to provide conforming contact during normal and high flexion activities. Patellar components are available in 6 sizes (diameters). Each size is available with different thickness.

There is no surface coating on any of the components of the Genius / Genuin Total Knee System.

**INDICATIONS FOR USE**

Indicated for use only with bone cement for patients suffering from: Severe knee joint pain, loss of mobility and disability due to: rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, Correction of functional deformities. Post-traumatic loss of knee joint contour, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy; Moderate valgus, Varus or flexion trauma. Knee fractures untreatable by other methods.

**COMPARISON TO TECHNOLOGY CHARACTERISTICS:**

The Genius / Genuin Total Knee System is equivalent to the predicate device with respect to intended use, device design, material and method of sterilization.

All the necessary performance test to determine the mechanical characteristics have been performed on the device i.e. Genius / Genuin Total Knee System.

**510(K) SUMMARY**

**PERFORMANCE DATA**

**Non-Clinical Performance**

The following tests have been conducted on the Genius / Genuin Total Knee Joint Replacement system:

- Cyclic Fatigue Testing of Metal Tibial Tray Component of Total Knee Joint Replacement (ASTM F1800-12)
- Evaluating Tibial Insert Endurance under High Flexion (220,000 cycles) (ASTM F2777-16)
- Determination of Total Knee Implant Femoral-Patellar Contact Pressure/Area (ASTM F1672- 14)
- Determination of Total Knee Implant Femoral-Tibial Contact Pressure/Area (ASTM F2083-12)
- Determination of Total Knee Replacement Constraint (ASTM F1223- 14)
- Accelerated Aging of UHMWPE after Gamma Irradiation in AIR (ASTM F2003-02)
- Locking mechanism strength test data; static anterior and posterior shear, static medial and lateral shear, static tensile pull off (ASTM F1814-15)
- 1m cycles testing (F/N curve) for shear resistance of tibial post in posterior stabilized tibial bearing (ASTM F1814-15)
- Range of Motion (ASTM F1223-14)
- UHMWPE Material Property Characterization
- Biocompatibility Testing as per ISO 10993-1:2018

**Clinical Performance Data/Information**

Not provided as the device is proven to be substantially equivalent to predicate device.

**CONCLUSION**

The Genius / Genuin Total Knee System components are identical to the predicate PFC Sigma Knee System components. Performance data and analyses demonstrate the device is as safe and effective and is substantially equivalent to the legally marketed predicate device.