April 13, 2026

HC Biologics, LLC
Onur Basol
Global Operations Director
1221 Brickell Ave. Suite 900
Miami, Florida 33131

Re: K260340
Trade/Device Name: HC BIOLOGICS OSTEOPOINT PEEK CAGES, HC BIOLOGICS OSTEOPOINT CERVICAL PEEK CAGES, HC BIOLOGICS OSTEOPOINT LUMBAR PEEK CAGES
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, OVE, MAX
Dated: January 8, 2026
Received: February 2, 2026

Dear Onur Basol:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

EILEEN CADEL -S for

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260340

Please provide the device trade name(s).

HC BIOLOGICS OSTEOPOINT PEEK CAGES;
HC BIOLOGICS OSTEOPOINT CERVICAL PEEK CAGES
HC BIOLOGICS OSTEOPOINT LUMBAR PEEK CAGES

Please provide your Indications for Use below.

HC BIOLOGICS OSTEOPOINT CERVICAL PEEK CAGES are made to be implanted into the appropriate vertebral section to help provide stability for spinal fusion after a diseased cervical disc producing neck and/or arm pain is removed during spinal decompression for patients who have had six weeks of non-operative treatment. Cervical PEEK Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level(C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Cervical PEEK Cages facilitate intervertebral body fusion in the cervical spine and are placed via the anterior approach and implanted with auto graft/autologous bone graft. They are to be used with supplemental fixation.

HC BIOLOGICS OSTEOPOINT LUMBAR PEEK CAGES are indicated for intervertebral body fusion at one or two contiguous levels in the lumbar spine from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) of lumbar spine with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have received at least six (6) months of prior non-operative treatment. The devices are designed to be used with supplemental fixation and autograft/autologous bone graft to facilitate fusion for each spinal region.

Please select the types of uses (select one or both, as applicable).

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

510(k) #: K260340

510(k) Summary

Prepared on: 2026-03-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	HC Biologics LLC
Applicant Address	1221 Brickell Avenue Suite 900 Miami, FL 33131 MIAMI FL 33131 United States
Applicant Contact Telephone	+13056007439
Applicant Contact	Mr. ONUR BASOL
Applicant Contact Email	onur.basol@hcbiologics.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	HC BIOLOGICS OSTEOPOINT PEEK CAGES; HC BIOLOGICS OSTEOPOINT CERVICAL PEEK CAGES HC BIOLOGICS OSTEOPOINT LUMBAR PEEK CAGES
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Bone Graft, Cervical
Regulation Number	888.3080
Product Code(s)	ODP, OVE, MAX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K252781	MSFX MIKRON PEEK CAGES	ODP, MAX

Device Description Summary

21 CFR 807.92(a)(4)

The HC BIOLOGICS OSTEOPOINT PEEK CAGES are intervertebral body fusion devices to be implanted into appropriate cervical and lumbar spine. HC BIOLOGICS OSTEOPOINT PEEK CAGES are composed of;
-HC BIOLOGICS OSTEOPOINT CERVICAL PEEK CAGES
-HC BIOLOGICS OSTEOPOINT LUMBAR PEEK CAGES
HC BIOLOGICS OSTEOPOINT CERVICAL PEEK CAGES are designed to maintain the height of the intervertebral space. It is used in surgical procedures where two vertebrae are connected or fused together to achieve fusion in spinal disorders. It supports bone fusion. Available in different shapes and sizes. In the cage body, PEEK (ASTM F2026) is used as raw material, and the pin, marker and screws are produced from Ti6Al4V ELI (ASTM F136). They are to be used with supplemental fixation, placed via anterior approach and implanted with auto graft/autologous bone graft.
HC BIOLOGICS OSTEOPOINT LUMBAR PEEK CAGES are designed to maintain the height of the intervertebral space. It is used in surgical procedures where two or three vertebrae are connected or fused together to achieve fusion in spinal disorders. It supports bone fusion. Available in different shapes and sizes. In the cage body, PEEK (ASTM F2026) is used as raw material, and the pin, marker and expansion mechanism are produced from Ti6Al4V ELI (ASTM F136). The devices are designed to be used with supplemental fixation and autograft/ autologous bone graft to facilitate fusion for each spinal region.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

HC BIOLOGICS OSTEOPOINT CERVICAL PEEK CAGES are made to be implanted into the appropriate vertebral section to help provide stability for spinal fusion after a diseased cervical disc producing neck and/or arm pain is removed during spinal decompression for

patients who have had six weeks of non-operative treatment. Cervical PEEK Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level(C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Cervical PEEK Cages facilitate intervertebral body fusion in the cervical spine and are placed via the anterior approach and implanted with auto graft/autologous bone graft. They are to be used with supplemental fixation.

HC BIOLOGICS OSTEOPOINT LUMBAR PEEK CAGES are indicated for intervertebral body fusion at one or two contiguous levels in the lumbar spine from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) of lumbar spine with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have received at least six (6) months of prior non-operative treatment. The devices are designed to be used with supplemental fixation and autograft/autologous bone graft to facilitate fusion for each spinal region.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The HC Biologics Osteopoint PEEK Cages have the same indications for use in comparison to the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The HC Biologics Osteopoint Peek Cages have same technological characteristics as the predicate device, including the materials, design, function, range of sizes, manufacturing processes, surgical techniques, and intended use.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

HC Biologics Osteopoint Peek Cages were tested biomechanically as sited below according to the regarding standards:
-ASTM F2077 :Static Axial Compression Test, Static Axial Compression Shear Test, Static Torsion Test, Dynamic Axial Compression Test, Dynamic Axial Compression Shear Test, Dynamic Torsion Test and
-ASTM F2267 :Subsidence

Based on the data presented in this submission, the subject device is determined to be substantially equivalent to the predicates in terms of its biomechanical performance. We can conclude that HC Biologics Osteopoint Peek Cages are as safe, as effective, and perform as well as the legal predicate devices identified in this submission.