December 5, 2024

KYOCERA Corporation
% Audrey Swearingen
Regulatory Affairs Consultant
Swearingen Regulatory Consulting, LLC
16856 Circle Hill Drive
Dexter, Missouri 63841

Re: K243444
Trade/Device Name: BIOCERAM AZUL® HEAD
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: November 6, 2024
Received: November 6, 2024

Dear Audrey Swearingen:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

RYAN TROMBETTA -S

Digitally signed by RYAN TROMBETTA -S
Date: 2024.12.05 16:30:09 -05'00'

For: Limin Sun, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243444

Device Name
BIOCERAM AZUL® HEAD

Indications for Use *(Describe)*
The BIOCERAM AZUL HEAD is a single use modular femoral head component for use in hip arthroplasty procedures for the following indications:
- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis,
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure,
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

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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510(k) Summary

BIOCERAM AZUL® HEAD

1. Submission Sponsor

KYOCERA Corporation
6 Takeda Tobadono-cho,
Fushimi-ku, Kyoto 612-8501
Japan
Contact: Ms. Yoshimi Amano
Title: Senior Manager of Regulatory Affairs Section, Medical Division

2. Submission Correspondent

Swearingen Regulatory Consulting, LLC
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Contact: Audrey Swearingen
Title: Regulatory Consultant

3. Date Prepared

December 4, 2024

4. Device Identification

Trade/Proprietary Name:	BIOCERAM AZUL® HEAD
Regulation Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Regulation Number(s):	888.3353
Product Code:	LZO
Class:	2
Classification Panel:	Orthopedic

5. Legally Marketed Predicate Device(s)

Device name:	Initia Total Hip System & BIOCERAM AZUL® HEAD
510(k) number:	K160895
Manufacturer:	KYOCERA Medical Corporation

KYOCERA Corporation is also using the Metal Head cleared in K160895 as a reference device, as the new BIOCERAM AZUL HEAD sizes are shared by the Metal Head.

6. Device Description

The BIOCERAM AZUL HEAD (the modified device) is identical to the unmodified predicate device in materials, taper system, articulating surface, packaging, sterilization and shelf life, but it differs from the unmodified predicate device in size variation. Labels are different only in reference to the model number and size.

The modified device is manufactured from the same high purity alumina matrix with zirconia reinforcement, which complies with ISO 6474-2. Two additional sizes (outer diameters) will be offered: 22 mm and 26 mm. There are 2 offsets (+0, +3 mm) for the 22 mm size and 2 offsets (+0, +3.5 mm) for the 26 mm size; and the current 28 mm head will be offered in an additional offset of +7 mm. These new ODs and offsets are the same or similar to those of the Metal Heads also cleared by K160895.

7. Indication for Use Statement

The BIOCERAM AZUL HEAD is a single use modular femoral head component for use in hip arthroplasty procedures for the following indications:
- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late-stage avascular necrosis,
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure,
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

8. Substantial Equivalence Discussion

The new BIOCERAM AZUL Head has the same has the same intended use as the predicate BIOCERAM AZUL Head. The new BIOCERAM AZUL Head has the same technological characteristics as the BIOCERAM AZUL Head of the predicate device, with respect to materials and design, except for these aspects:
- Size 22 mm OD now offered in +0 and +3 mm offsets;
- Size 26 mm OD now offered in +0 and +3.5 mm offsets;
- Size 28 mm OD now offered in +7 mm offset

However, these new sizes and offsets are the same or very close to those of the metal heads also cleared in K160895. The worst-case design was tested to demonstrate equivalency to the predicate device. The minor differences of the subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of modified BIOCERAM AZUL HEAD and to show substantial equivalence to the predicate device, KYOCERA Corporation conducted the following performance bench tests in accordance with internal procedures and international standards shown below. The modified

device passed the testing, supporting its safety and effectiveness, and its substantial equivalence to the predicate device.

- Static compression burst test (ISO 7206-10)
- Post-fatigue static compression burst test (ASTM F2345 / ISO 7206-10)
- Static Pull-off test (ISO 7206-10)
- Static torsion test (ISO 7206-13)

10. Statement of Substantial Equivalence

The modified BIOCERAM AZUL HEAD has the same intended use and the same or similar technological characteristics as the predicate device. The new sizes represented by the subject device were successfully evaluated through appropriate safety and performance testing, demonstrating that the subject device does not raise any new questions of safety and effectiveness when compared to the predicate device, and is at least as safe and effective as the predicate device. Therefore, the modified BIOCERAM AZUL HEAD is substantially equivalent to the predicate BIOCERAM AZUL HEAD.