August 21, 2026

Mediclus Co., Ltd.
Ku Da Hyeon
1210, 134, Gongdan-Ro, Heungdeok-Gu
Cheongju-Si, 28576
Republic Of Korea

Re: K262074
Trade/Device Name: Any-Zircos
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: June 19, 2026
Received: June 22, 2026

Dear Ku Da Hyeon:

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,

JOYCE C. LIN -S

FDA

for Michael Adjodha, M. Ch.E., RAC, CQIA
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental 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.	K262074

Please provide the device trade name(s).

Any-Zircos

Please provide your Indications for Use below.

Any-Zircos is indicated for the production of inlays or onlays, 3-unit bridges and full crowns.

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)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☐ Adults (22 years old and greater)

510(k) Summary

K262074

This summary of 510(K) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: August 21, 2026

1. Submitter/Contact Person

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3. Device

- Trade Name: Any-Zircos
- Common Name: Powder, Porcelain
- Classification Name: Powder, Porcelain
- Product Code: EIH
- Regulation Number: 872.6660

4. Predicate Device:

1. LUXEN 5G by DENTALMAX CO., LTD (K241151)
2. LUXEN smile by DENTALMAX CO. LTD (K171585)

5. Description:

Any-Zircos is a dental zirconia block classified as Type2, Class 4a according to ISO 6872, and is a zirconia ceramic material used for the fabrication of dental restorations such as inlays artificial teeth crowns and, bridges.

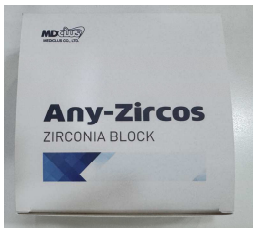
Any-Zircos is available in Discs with a various width, thickness and shades.

6. Indication for use:

Any-Zircos is indicated for the production of inlays or onlays, 3-unit bridges and full crowns.

7. Basis for Substantial Equivalence

7.1. Comparison Chart

		Subject Device	Predicate Device 1	Predicate Device 2	Equivalence evaluation
Manufacturer		MEDICLUS Co., Ltd.	DENTALMAX CO., LTD	DENTALMAX CO., LTD	-
Product Name		Any-Zircos 	LUXEN 5G 	LUXEN smile 	-
510k#		-	K241151	K171585	-
Product Code		EIH	EIH	EIH	-
Material		ZrO2, Y2O3, HfO2, Al2O3 and other oxides	Zirconia Powder Zpex ZrO2+HfO2+Y2O3 + various color powders	Zpex Smile ZrO2+HfO2+Y2O3 and others	Similar
Indications for Use		Any-Zircos is indicated for the production of inlays or onlays, 3-unit bridges and full crowns.	LUXEN 5G is indicated for the production of all ceramic inlays, multi units bridges, onlays, and veneers without zirconium dioxide frameworks.	LUXEN Smile is indicated for the production of of full ceramic crowns, onlays, 3-bridges and inlay bridges (anterior and molar).	Similar
Intended User		Licensed Dentist or Dental Professional	Licensed Dentist or Dental Professional	Licensed Dentist or Dental Professional	Same
Principles of Operation		Zirconia oxide blank is a material for crowns and bridges fabricated by CAD/CAM milling.	Zirconia oxide blank is a material for crowns and bridges fabricated by CAD/CAM milling.	Zirconia oxide blank is a material for crowns and bridges fabricated by CAD/CAM milling.	Same
Classification		Type II Class 4a	Type II Class 5	Type II Class 4b	Similar
Technological Characteristics	**Standard Conformed**	ISO 6872	ISO 6872	ISO 6872	Same
	Uniformity	Pass	-	-	Similar
	Radioactivity	0.001 27	≤ 1.0 Bq·g -1	-	

	(Bq/g)				
	Chemical solubility (μg/㎠)	25.9	< 100 μg/cm2	0 μg/㎠	
	Flexural strength	Mean 1 241.1	>800Mpa	770 ± 66 MPa	
	Linear thermal expansion coefficient	Avg 10.85 x 10^{-6}	-	10.3 X 10-6K -1	
Sterile		Non-sterile	Non-sterile	Non-sterile	Same
Biocompatibility		Biocompatible	Biocompatible	Biocompatible	Same
Classification		Externally communicating device in oral mucosa, enamel, and dentin; and contact duration of C-long term (>30d)	Externally communicating device in oral mucosa, enamel, and dentin; and contact duration of C-long term (>30d)	Externally communicating device in oral mucosa, enamel, and dentin; and contact duration of C-long term (>30d)	Same

7.2. Comparison Chart

The subject device has similar indications for use and the technological characteristics as the predicate device. The minor raw materials are different between the devices but the performance and the biocompatibility test results show that it does not raise new questions of safety and effectiveness.

8. Non-Clinical Testing

- Performance Tests including
  - Appearance, Dimension, Package, Uniformity, Extraneous materials, Radioactivity, Chemical solubility, Flexural strength, Flexural strength after accelerated aging, Linear thermal expansion coefficient, Monoclinic phase in accordance with ISO 6872.
- Biocompatibility tests in accordance with ISO 10993-5, 10, 11 and 23.

9. Conclusion

The subject device and the predicate device have the same intended use and have the similar technological characteristics. Based on the similarities and the test results, we conclude that the subject device is substantially equivalent to the predicate device.