August 1, 2025

Shandong Huge Dental Material Corporation
Maggie Zheng
Regulatory Affairs Manager
No. 68 Shanhai Road, Donggang District
Rizhao City, 276800
CHINA

Re: K251252
Trade/Device Name: NOBILCAM IMPAK Disc
Regulatory Class: Unclassified
Product Code: MQC
Dated: July 17, 2025
Received: July 18, 2025

Dear Maggie Zheng:

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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, 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.	K251252 ?

Please provide the device trade name(s). ?

NOBILCAM IMPAK Disc

Please provide your Indications for Use below. ?

The NOBILCAM IMPAK Disc is a heat cured, moldable, acrylic compound for use in the fabrication of dental appliances and dental prostheses devices including TMJ splint appliances, nightguards, bruxism appliances and other devices as prescribed.

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

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

K251252

510 (k) Summary

This summary of 510(k) for the subjective device equivalence information is being submitted in accordance with the requirements of 21 C.F.R. 807.92.

1. **Date Summary Prepared:** August 1, 2025

2. **Submitter Information:**

Owner's Name	Shandong Huge Dental Material Corporation
Address	No. 68 Shanhai Road, Donggang District, Rizhao City, Shandong Province, 276800, P.R. China
Telephone	0086 633 2277268
Fax	0086 633 2277298
Contact Person	Ms. Maggie Zheng
Contact Title	Regulatory Affairs Manager
E-mail	zhengxy@hugedent.com

3. **Device Name**

Trade name: NOBILCAM IMPAK Disc

Common name: IMPAK Disc

Classification name: Mouthguard, Prescription

Regulation Number: None

Regulatory Class: Unclassified

Product Code: MQC

4. **Predicate and Reference Device Information**

Owner/Operator	Device Trade Name	510 (k) No.	Product Code	Classification Name	Predicate / Reference
ASTRON DENTAL CORPORATION	Clearsplint Disc	K111828	MQC	Mouthguard, Prescription	Predicate (Primary)
GC AMERICA, INC	Pattern Resin LS	K003817	EBG	Crown and Bridge, Temporary, Resin	Reference

Note: The main reason for inclusion of the reference device, Pattern Resin LS (K003817), is to support similarities in composition of materials to the subject device.

5. Description of Device

The NOBILCAM IMPAK Disc contains a cured disc, to be used in a CAD/CAM machine to produce an occlusal splint for suffering patients. NOBILCAM IMPAK Disc is mainly composed of acrylic resin and manufactured through compression molding. Depending on the different CAD/CAM machines used for the product, NOBILCAM IMPAK Disc is designed into various specifications and shades to meet different needs.

6. Indications for Use

The IMPAK Disc is a heat cured, moldable, acrylic compound for use in the fabrication of dental appliances and dental prostheses devices including TMJ splint appliances , nightguards, bruxism appliances and other devices as prescribed.

7. Summary of Physical and Chemical Properties Tests

The physical properties of the subject device, including Appearance, Dimension, Color Stability, Water Sorption, Water Solubility, Tear strength, Hardness, Ultimate flexural strength and Flexural modulus were determined and tested according to ISO 20795-2:2013, ADA ANSI Standard No. 99-2001 (R2023), ADA ANSI Standard No. 139-2020 and internal inspection standard. Bench testings were performed on the subject device and the predicate device, the test results demonstrated the substantial equivalence when compared to the predicate device.

8. Technological Characteristics Comparison

All components of the subject device are based upon industry well-known chemistry. The following table shows the significant technological characteristics for the subject device and indicates the following similarities and differences with the predicate and reference devices:

Technological Characteristics	Subject device	Predicate device K111828	Reference device K003817
Product Name	NOBILCAM IMPAK Disc	Clearsplint Disc	Pattern Resin LS
Company name	Shandong Huge Dental Material Corporation	ASTRON DENTAL CORPORATION	GC AMERICA, INC.

Technological Characteristics	Subject device	Predicate device K111828	Reference device K003817
Product Name	NOBILCAM IMPAK Disc	Clearsplint Disc	Pattern Resin LS
Company name	Shandong Huge Dental Material Corporation	ASTRON DENTAL CORPORATION	GC AMERICA, INC.
Main Composition	Acrylic compound	Acrylic compound	Acrylic compound
Physical Form	Disc form	Disc form	/
Indications of Use	The IMPAK Disc is a heat cured, moldable, acrylic compound for use in the fabrication of dental appliances and dental prostheses devices including TMJ splint appliances, nightguards, bruxism appliances and other devices as prescribed.	It is a heat cured, moldable, acrylic compound for use in the fabrication of dental appliances and dental prostheses devices including TMJ splint appliances, night guards, bruxism appliances and other devices as prescribed.	/
Prescription/over-the-counter use	Prescription	Prescription	/
Sterility	Non-sterile	Non-sterile	/
Storage Condition	Store in original package in a cool, dry, well-ventilated area. Keep away from sources of ignition and light.	Store at room temperature(26˚C) in the original packaging in a cool dry place away from sources of ignition and heat.	/
Package form	Packaged in box	Packaged in box	/
Physical Properties	The subject device and predicate device have substantially equivalent physical properties.		/

The indications of the subject device are similar to that of 510(k) cleared predicate device. Based on the similarities in indications for use, the subject device has demonstrated substantial equivalence to the predicate device.

Based on ISO 20795-2:2013, ADA ANSI Standard No. 99-2001 (R2023), ADA ANSI Standard No. 139-2020 and internal inspection standard, technological characteristics, physical properties, performance testing are carried to compare the subject

device with predicate device. According to test results, the subject device has similar technological characteristics with the predicate device.

9. Summary of Non-clinical testing

The physical properties of the subject device were determined and tested according to ISO 20795-2:2013, ADA ANSI Standard No. 99-2001 (R2023), ADA ANSI Standard No. 139-2020 and internal inspection standard, and the test results demonstrated the qualification and substantial equivalence when compared to the predicate device.

Additionally, the subject device is substantially equivalent to the predicate and reference devices. The compositions of the subject device do not contain any non-conventional chemicals compared to the legally marketed predicate and reference devices. Biocompatibility tests were performed fully following the ISO 7405 and ISO 10993 standards, including Cytotoxicity, Irritation, Sensitization, Genotoxicity, Acute systemic toxicity and Subchronic Toxicity, and test results are sufficient to prove the subject device is substantially equivalent to the predicate device.

10. Clinical Performance Data

Clinical test is not applicable.

11. Conclusions

Based on the indications for use, technological characteristics, performance testing and comparison to predicate device, the subject device has demonstrated substantial equivalence. Shandong Huge Dental Material Corporation concludes that the subject device is substantially equivalent to the predicate device described herein.