July 31, 2026

3bfab Teknoloji A.s.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
1887 Whitney Mesa Dr.
Suite 1960
Henderson, Nevada 89014

Re: K262681
Trade/Device Name: NanoCeram Resin
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture relining, repairing, or rebasing resin
Regulatory Class: Class II
Product Code: EBI, EBF, PZY
Dated: July 30, 2026
Received: July 30, 2026

Dear Dave Yungvirt:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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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)*
K262681

Device Name
Nanoceram Resin

Indications for Use *(Describe)*
NanoCeram Resin is a light-curing 3D printed material designed as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. NanoCeram Resin material is used in the fabrication of permanent restorations such as inlays, onlays, veneers and full crown restorations. NanoCeram Resin is a tooth shade ceramic-hybrid resin used for the fabrication of hybrid denture prosthetics, implant supported denture prosthetics, monolithic full and partial removable denture and preformed denture teeth to be used in a denture.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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# 510(k) Summary

510(k) #: K262681

**Prepared on**: 22 July 2026

**Contact Details**

| | |
|---|---|
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**Device Name**

| | |
|---|---|
| Device Trade Name | NanoCeram Resin |
| Common Name | Denture relining, repairing, rebasing resin |
| Classification Name | Resin, Denture, Relining, Repairing, Rebasing |
| Regulation Number | 872.3760 |
| Product Code(s) | EBI, EBF, PZY |

**Legally Marketed Predicate Devices**

| Predicate K# | Trade Name | Product Code |
|---|---|---|
| K240688 | RODIN Titan 3D Resin | EBI, EBF |
| K230445 | OnX Tough | EBI, PZY |

**Device Description Summary**

NanoCeram Resin is a light-curable, ceramic-filled, methacrylate-based photopolymer resin intended for the additive manufacturing of permanent and temporary dental restorations and prosthetic components through digital light processing (DLP) three-dimensional printing technology. The device is supplied as a liquid resin formulation that undergoes photopolymerization when exposed to a controlled light source operating at a wavelength of 385 nm, resulting in the formation of a solid, highly cross-linked polymer restoration. The material is designed for use within a validated digital dental workflow consisting of intraoral scanning, computer-aided design (CAD), print file generation, additive manufacturing, cleaning, post-curing, finishing, and clinical placement. NanoCeram Resin is intended exclusively for use with manufacturer-approved software, printing systems, and post-curing equipment to ensure consistent restoration quality, mechanical performance, and biocompatibility.

NanoCeram Resin consists of a ceramic-reinforced methacrylate resin system containing Bisphenol A Ethoxylate Dimethacrylate, Triethylene Glycol Dimethacrylate, dental glass fillers, photoinitiators, and silica-containing constituents. The inorganic filler loading ranges from approximately 50% to 70%, providing enhanced mechanical strength, rigidity, wear resistance, and esthetic characteristics suitable for long-term restorative applications. The resin formulation is available in multiple tooth shades, including A1, A2, A3.5, B1, B2, B3, B4, C1, C2, D2, BL, and OM3 allowing fabrication of restorations that closely match natural dentition.

**Intended Use/Indications for Use**

NanoCeram Resin is a light-curing 3D printed material designed as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. NanoCeram Resin material is used in the fabrication of permanent restorations such as inlays, onlays, veneers and full crown restorations. NanoCeram is a tooth shade ceramic-hybrid resin used for the fabrication of hybrid denture prosthetics, implant supported denture prosthetics, monolithic full and partial removable denture and preformed denture teeth to be used in a denture.

**Indications for Use Comparison**

NanoCeram Resin has indications for use that are substantially equivalent to those of the identified predicate devices. Like Rodin Titan 3D Resin (K240688), it is a prescription, tooth-shade ceramic-hybrid resin indicated for the fabrication of permanent anterior and posterior restorations, including inlays, onlays, veneers, and full crowns, as well as hybrid denture prosthetics, implant-supported denture prosthetics, monolithic full and partial removable dentures, and preformed denture teeth. These removable prosthetic indications are also consistent with SprintRay OnX Tough (K230445). The description of NanoCeram Resin as a light-curing 3D printed material represents a technological characterization rather than a difference in intended use. Accordingly, the proposed indications are consistent with those of the predicate devices and do not raise new questions of safety or effectiveness.

**Technological Comparison**

| **Device & Predicate Device(s):** | **NanoCeram Resin** | **Rodin Titan 3D Resin K240688** | **Onx Tough K230445** |
|---|---|---|---|
| Manufacturing technology | 3D liquid (light cured) print resin for dental CAD/CAM | 3D liquid (light cured) print resin for dental CAD/CAM | 3D liquid (light cured) print resin for dental CAD/CAM |
| Material | Methacrylate-based resin with ceramic/nano-ceramic filler system | Methacrylate-based resin with filler/pigments | Methacrylate-based ceramic-hybrid resin |
| Fabrication method | DLP/LCD vat photopolymerization | Additive manufacturing | Additive manufacturing |
| Wavelength | 385-405 nm | 385-405 nm | 385-405 nm |
| Thickness | 100 µm | 100 µm | 100 µm |
| Material Shades | Various shades | Various shades | Various shades |

| Device & Predicate Device(s): | NanoCeram Resin | Rodin Titan 3D Resin K240688 | Onx Tough K230445 |
|---|---|---|---|
| Composition | Bisphenol A Ethoxylate Dimethacrylate, Triethylene Glycol Dimethacrylate, dental glass fillers, photoinitiators, and silica-containing constituent | UDA, HEMA, BHT, TPO, TF 3.0, YbF3, Fumed Silica | Methacrylate Monomer/oligomers that polymerized to Methymethacylate Based polymer. |
| Flexural strength (≥65 MPa) | 115.5-122.3 | 136 | 71.03 ± 1.45 |
| Flexural modulus (>2000 MPa) | 4421-4553 | Not disclosed | 2271 ± 118 |
| Water sorption (≤32 µg/mm$^3$) | 19-26 | 26 | 31 ± 1 |
| Solubility (≤5 µg/mm$^3$) | 0.2-0.8 | 0.1 | 4.0 ± 0.5 |
| Residual methyl methacrylate monomer (<1.0 mg) | Pass | Pass | Pass |
| Max stress intensity factor (≥1.9 MPA m$^{1/2}$) | 3.91-4.15 | 4.15 | 3.176 ± 0.209 |
| Total fracture work (>900 J/m$^3$) | 1060-1370 | 2442 | 945 ± 88 |
| Opacity | 82.36% - 82.90% @ 1mm thickness | 70% @ 1mm thickness | Not disclosed |
| Sterile | Non-sterile | Non-sterile | Non-sterile |
| Shelf life | 2 yrs. | 2 yrs. | 2 yrs. |

The differences are limited to the specific resin and ceramic filler composition and do not affect the intended use, clinical function, or fundamental mode of action. Such formulation differences are common among legally marketed dental resins and do not raise new questions of safety or effectiveness. Substantial equivalence is supported through bench performance testing, chemical characterization, and biocompatibility data demonstrating comparable safety and performance.

**Non-Clinical and/or Clinical Tests Summary & Conclusions**

To demonstrate safety and effectiveness of NanoCeram Resin and to show substantial equivalence to the predicate devices, 3BFAB completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. NanoCeram Resin passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device.

- Biocompatibility safety testing per ISO 10993
- Dentistry performance testing per ISO 4049, ISO 10477, ISO 20795-1, and ISO 22112
- Labelling requirements per ISO 15223-1
- Risk Management process per ISO 14971

No clinical tests were required to demonstrate substantial equivalence.

NanoCeram Resin, the subject device, has the same intended use and similar technological characteristics that have been compared and contrasted with the chosen predicate devices, and that the subject does not raise additional questions regarding its safety and effectiveness. Non-clinical testing has demonstrated NanoCeram Resin is as safe and effective as the predicate device. Therefore, through intended use, technology, and performance testing, NanoCeram Resin is substantially equivalent to the predicate devices.