March 5, 2024

Yamahachi Dental MFG., Co.
℅ Takahiro Haruyama
President
Globizz Corporation
1411 W. 190th St.
Suite 200
Gardena, California 90248

Re: K233859
Trade/Device Name: BASIS FLOW II
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: December 5, 2023
Received: December 6, 2023

Dear Takahiro Haruyama:

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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233859

Device Name
BASIS FLOW II

Indications for Use *(Describe)*
The BASIS FLOW II is intended for fabrication or repair of the denture base.

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.

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YAMAHACHI DENTAL MFG., CO.
MANUFACTURERS, IMPORTERS AND
EXPORTERS OF DENTAL PRODUCTS

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510(k) Summary

Prepared on 2024-03-01

510(k) #: K233859

CONTACT DETAILS:

Applicant Name: YAMAHACHI DENTAL MFG., Co.

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Applicant Contact Telephone: +81-533-57- 7121

Applicant Contact: Shuhei Hirota

Applicant Contact Email: hirota@yamahachi -dental.co.jp

Device Name

Device Trade Name: BASIS FLOW II

Common Name: Dental Resin

Classification Name: EBI. Denture Relining, Repairing, Rebasing Resin.

Regulation Number: 872.3760

Predicate Device

Predicate #	Predicate Trade Name	Product Code
K131036 (Primary predicate)	Yamahachi Denture Base Resins –Basis FLOW	EBI

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E-mail:box@yamahachi-dental.co.jp

1. Device Description

BASIS FLOW II is supplied as components in powder and liquid form. The powder is primarily a polymer of polymethyl methacrylate (PMMA) with small quantities of initiator and color pigments. The liquid is primarily the monomer methyl methacrylate (MMA) with small quantities of a cross-linking agent and activator.

To fabricate the denture base, the powder and liquid materials are mixed and stirred to create a dough state that is packed or poured into a mold, saddle, or core. The resin then cures in a self-curing process (pressure vessel or via quick-setting).

2. Indications for Use

The BASIS FLOW II is intended for fabrication or repair of the denture base.

3. Technological Comparison

	Subject Device	Predicate Device	Differences
Device Name	Basis FLOW II	Basis FLOW	
510(k) number	K233859	K131036	
Manufacturer	Yamahachi Dental	Yamahachi Dental	
Regulation	872.3760	872.3760	**Same**
Product Code	EBI	EBI	**Same**
Device Description	Self-curing denture base material intended as a pouring acrylic.	Self-curing denture base material intended as a pouring acrylic.	**Same**
Intended Use	Materials for the gum portion of dentures. It may be used as a material for the plate portion of orthodontic appliances.	Materials for the gum portion of dentures. It may be used as a material for the plate portion of orthodontic appliances.	**Same**
Product State	Polymer powder & monomer liquid	Polymer powder & monomer liquid	**Same**
Flexural Strength	92.5 MPa	80.1 MPa	*Similar*
Flexural Modulus	3,310 MPa	1,657 MPa	*Similar*
Residual Monomer	3.4%	4.2%	*Similar*
Sorption	24.5 μg/mm^3	18.8 μg/mm^3	*Similar*
Solubility	0.7 μg/mm^3	1.8 μg/mm^3	*Similar*

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4. Nonclinical Performance Data

Basis FLOW II was tested in accordance with ISO 20795-1:2013 Dentistry - Base Polymers - Part 1: Denture Base polymers (Type 2, Class 2) and ISO 20795-2:2013 Dentistry - Base Polymers - Part 2: Orthodontic base polymers (Type 1).

The subject device and predicate device have similar levels of flexural strength, flexural modulus, residual monomer, sorption, and solubility. Both meet ISO standards.

5. Substantial Equivalence Summary / Conclusion

BASIS FLOW II has the same intended use and the same technological characteristics as the predicate device. The only difference is the addition of one ingredient (polymerization inhibitor) to the product components. This addition does not affect product performance, safety, or effectiveness, as supported by meeting the standards of ISO 20795-1.

In conclusion, BASIS FLOW II warrants a finding of substantial equivalence to the legally marketed device BASIS FLOW, one of the bundled devices of Yamahachi Denture Base Resins (K131036), and of proper clearance for premarketing activities in the United States.

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Appendix: The Configurations and colors of the subject device, BASIS FLOW II

BASIS FLOW II (Powder, 40G, LF PINK)
BASIS FLOW II (Powder, 40G, CLEAR)
BASIS FLOW II (Powder, 40G, LF α)
BASIS FLOW II (Powder, 40G, V PINK)
BASIS FLOW II (Powder, 40G, O PINK)
BASIS FLOW II (Powder, 500G, LF PINK)
BASIS FLOW II (Powder, 500G, CLEAR)
BASIS FLOW II (Powder, 500G, LF α)
BASIS FLOW II (Powder, 500G, V PINK)
BASIS FLOW II (Power, 500G, O PINK)
BASIS FLOW II (Powder, 10KG, LF PINK)
BASIS FLOW II (Powder, 10KG, CLEAR)
BASIS FLOW II (Powder, 10KG, LF α)
BASIS FLOW II (Power, 10KG, V PINK)
BASIS FLOW II (Powder, 10KG, O PINK)
BASIS FLOW II (Liquid, 25ML)
BASIS FLOW II (Liquid, 500ML)
BASIS FLOW II (Liquid, 4L)
BASIS FLOW II (Liquid, 17L)
BASIS FLOW II (Powder + Liquid set, 40G* 25ML, LF PINK)
BASIS FLOW II (Powder + Liquid set, 40G*25ML, CLEAR)
BASIS FLOW II (Powder + Liquid set, 40G*25ML, LF α)
BASIS FLOW II (Powder + Liquid set, 40G*25ML, V PINK)
BASIS FLOW II (Powder + Liquid set, 40G*25ML, O PINK)
BASIS FLOW II (Powder + Liquid set, 650G*500ML, LF PINK)
BASIS FLOW II (Powder + Liquid set, 650G*500ML, CLEAR)
BASIS FLOW II (Powder + Liquid set, 650G*500ML, LF α)
BASIS FLOW II (Powder + Liquid set, 650G*500ML, V PINK)
BASIS FLOW II (Powder + Liquid set, 650G*500ML, O PINK)