DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 14, 2015

Sun Medical Co. Ltd.
c/o Carrie Hetrick, D.D.S.
Emergo Group
816 Congress Avenue, Suite 1400
Austin, Texas 78701

Re: K143265
Trade/Device Name: Acrylic Block
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture relining, repairing, or rebasing resin
Regulatory Class: II
Product Code: EBI
Dated: March 6, 2015
Received: March 10, 2015

Dear Dr. Hetrick:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143265

Device Name
Acrylic Block

Indications for Use *(Describe)*
Acrylic Block is a cured base acrylic resin that is indicated for use to fabricate 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

for

Acrylic Block

1. Submission Sponsor

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3. Date Prepared

April 14, 2015

4. Device Identification

Trade/Proprietary Name:	Acrylic Block
Common/Usual Name:	Denture Base Resin
Classification Name:	Denture Relining, Repairing, or Rebasing Resin
Classification Regulation:	21 CFR § 872.3760
Product Code:	EBI
Device Class:	Class II
Classification Panel:	Dental

5. Legally Marketed Predicate Device(s)

Yamahachi Dental Manufacturing Co., Yamahachi Denture Base Resins– K131036

6. Device Description

The Acrylic Block is a solid block of an acrylic polymer block that includes small quantities of color pigments. This Acrylic Block is a high polymer material made from quality poly methyl methacrylate. Poly (methyl methacrylate) is commonly used for thermopolymerizable

acrylic resin denture bases because of its properties, including color and durability. In vitro tests have also shown its biocompatibility and enhancement of flexural behavior properties.

To fabricate the denture base, the Acrylic Block is milled by a milling machine utilizing the CAM data. After a 3D denture image is structured using the 3D CAD software, the artificial teeth are factored out, and a 3D denture base image is obtained. The Acrylic Block is then milled to the shape of the denture base. The artificial teeth are then bonded to the milled denture base using a bonding material and polished.

7. Indication for Use Statement

Acrylic Block is a cured base acrylic resin that is indicated for use to fabricate a denture.

8. Substantial Equivalence Discussion

The following table compares the Acrylic Block to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	**Sun Medical Co., Ltd.**	**Yamahachi Dental Manufacturing Co.**
Trade Name	**Acrylic Block**	**Yamahachi Denture Base Resins**
510(k) Number	K143265	K131036
Product Code	EBI	EBI
Regulation Number	21 CFR § 872.3760	21 CFR § 872.3760
Regulation Name	Denture Base Resin	Denture Base Resin
Device Description	It is used for creation of a denture base with a computer-aided-design and computer-aided-manufacturing unit.	Traditional heat-cure and microwave-cure acrylic resign for total or partial denture base and for removable prosthesis
Indications for Use	Acrylic Block is a cured base acrylic resin that is indicated for use to fabricate a denture.	Yamahachi Denture Base Resins is a system of heat- and self-cure acrylic polymers intended for fabrication or repair of the denture base.
Composition of Material – the chemical composition of the device	Block made by Methyl methacrylate (MMA) monomer	Polymer powder and monomer liquid
Polymerization (Curing) Method	Acrylic Blocks polymerization is completed by heat curing method at 20° C to 80° C.	Water Bath: Immerse flask in water & slowly raise to boiling over 30 min, boil 30-40 min, air cool 30 min (Basis & Basis HI); Curing: Immerse flask in boiling water 30 min (Basis TC)
Components	PMMA, initiator, pigments	Powder: PMMA, MMA (Basis Hi), Initiator, pigments Liquid:-MMA, Crosslinker, activator (Basis TC)
Standards of Conformity	ISO 9001:2007, ISO 13485:2003,	ISO 9001:2007, ISO 13485:2003,

Manufacturer	Sun Medical Co., Ltd.	Yamahachi Dental Manufacturing Co.
Trade Name	**Acrylic Block**	**Yamahachi Denture Base Resins**
	ISO 14971	ISO 14971
Biocompatibility	ISO 10993-1, ISO 7405	ISO 10993-1, ISO 7405
Physical Properties	ISO 20795-1, ANSI/ADA 12:2002	ISO 20795-1

9. Non-Clinical Performance Data

Extensive testing has been performed on the subject denture base resin to demonstrate compliance with EN ISO 7405:1997 Dentistry; Preclinical evaluation of biocompatibility of medical devices used in dentistry, Test methods for dental materials; and EN ISO 1567:1995 Denture Base Polymers. The following testing has been performed to support substantial equivalence:

Biocompatibility –The biocompatibility of the Acrylic Block was evaluated in accordance with ISO 7405:2008, ISO 10993-1: 2009 and guidance document entitled Blue Book Memo, G95-1, Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing. Under these, for the stated indications for use, the device was classified as a permanent exposure (C), surface-contacting device in contact with mucosal membranes. The Sun Medical Acrylic Block biocompatibility was tested for the following with the final results.

- Cytotoxicity (MEM Elution Test) – The Acrylic Block was found to be non-cytotoxic and all test method acceptance criteria were met per ISO 10993-5, JIS T 6001, Yakushokukihatsu No. 0301-20.
- Skin Sensitisation (Guinea Pig Maximization) - Acrylic Block is considered to cause no sensitization under the experimental conditions of this study per ISO 10993-10, JIST T 6001:2012 Yakushokukihatsu No. 0301-1, and Yakushokukihatsu No. 0301-20.
- Intracutaneous Reactivity - Acrylic Block caused no signs of irritation, met the requirements of the test, and is classified as not irritant per ISO 10993-10, JIS T 6001, and Yakushokukihatsu No. 0301-20.
- Subchronic Toxicity - Acrylic Block is considered to not cause significant systemic toxicity under the experimental conditions of this study per ISO 10993-11, JIS T 6001, Yakushokukihatsu No. 0301-1. And Yakushokukihatsu No. 0301-20.
- Genotoxicity (In Vitro Mammalian Chromosome Aberration Test) - Acrylic Block extract is considered to be non-clastogenic under the experimental conditions of this study per ISO 10993-3, JIST T 6001:2012 Yakushokukihatsu No. 0301-1, and Yakushokukihatsu No. 0301-20.
- Genotoxicity Bacterial Reverse Mutation (AMES) Test - Acrylic Block was considered non-mutagenic (non-genotoxic and non-clastogenic) under the experimental conditions of this study per ISO 10993-3, JIST T 6001:2012 Yakushokukihatsu No. 0301-1, and Yakushokukihatsu No. 0301-20.

Mechanical Testing – Performance testing of the Acrylic Block included testing for denture base polymers and copolymers in ISO 20795-1, Dentistry -- Base polymers -- Part 1: Denture

base polymers, ISO 22112 Dentistry – Artificial teeth for dental prostheses, and ANSI/ADA Specification No. 12 – Denture Base Polymers.

Performance testing was conducted to evaluate the mechanical properties of the Acrylic Block. Specimens for each test were made according to the *ADA/ANSI Specification No. 12: 2002 (Reaffirmed 2008) Denture Base Polymers* to evaluate the subject devices flexural and tensile strengths, and fracture toughness. The subject device was also examined the ADA specification for surface characteristics, color, translucency, freedom from porosity, flexural strength, flexural modulus, residual methyl methacrylate monomer, sorption and solubility. It was concluded that the Acrylic Block met all acceptance criterion and hence are substantially equivalent to Yamahachi Denture Base Resins in terms of mechanical properties. It was also concluded that the Sun Medical Acrylic Block show a substantially similar performance other predicate denture base resins during non-clinical bench testing.

Risk Management – Risk Analysis was conducted according to ISO 14971, and the outcomes of these risks are considered acceptable, and that all potential risks have been mitigated to the lowest form.

PMMA resin continues to be the universal, versatile polymer in prosthetic dentistry. The Acrylic Block has the same biological performance as predict PMMA resins.

As part of demonstrating that the Acrylic Block is substantially equivalent to predicate devices that are subject to this 510(k) submission, Sun Medical Co., Ltd. completed a number of tests. The Acrylic Block meets all the requirements for overall design and biocompatibility confirms that the output meets the design inputs and specifications. The Acrylic Block passed all testing stated above as shown by the acceptable results obtained in accordance with national and international standards.

10. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years and there are no adverse reactions. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

The Acrylic Block has the same or similar intended use, indications, principles of operation, and technological characteristics as the predicate devices. The Acrylic Block, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices in terms of intended use, design, materials, and function.