The Myerson Company Limited
Cindy Buchoon-Legendre
QA/RA Coordinator
3 Trinity Avenue
Laventille,
TRINIDAD & TOBAGO

November 2, 2017

Re: K172407
Trade/Device Name: Duracetal
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: August 18, 2017
Received: August 23, 2017

Dear Cindy Buchoon-Legendre:

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 (DICE) 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" (21 CFR 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 (DICE) 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,

Mary S. Runner -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.0 *INDICATIONS FOR USE STATEMENT*

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)*
K172407

Device Name
Duracetal

Indications for Use *(Describe)*
The product is a thermoplastic dental resin intended for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

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.

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510(k) summary

SUBMITTER

Name: The Myerson Company Limited

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Phone: 1 868 623 1007

Fax number: 1 868 627 4594

Name of contact person: Cindy Buchoon-Legendre

Date the corrected summary was prepared: Aug 24 2017

DEVICE

Trade name – Duracetal

Common name – thermoplastic dental resin

Classification name – resin, denture, relining, repairing, rebasing (21 CFR 872.3760, Product Code EBI)

510K # of new product: K172407

PREDICATE DEVICE
Legally marketed device to which the Myerson Company Limited is claiming equivalence:

Company Name: The Myerson Company Limited

Trade name – Duraflex

Common name – thermoplastic dental resin

Classification name – resin, denture, relining, repairing, rebasing (21 CFR 872.3760, Product Code EBI)

510K# of predicate: K063626

DEVICE DESCRIPTION

Description of the device: The product is a thermoplastic dental resin intended for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

Explanation of how the device functions: the resin is processed at a dental lab to make an oral device as determined by a dental practitioner.

Scientific concepts that form the basis for the device: The material is used to make dental devices which work to temporarily replace or support part of the anatomy of the oral cavity.

Significant physical and performance characteristics of the device: The material is an acetal thermoplastic resin. The pellet version of the resin are melted and reshaped to form the dental device. The disc version of the material is milled to form the dental device.

INDICATIONS FOR USE

Intended use of the device: The product is a thermoplastic dental resin intended for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

Description of the disease or conditions that the device will treat, prevent or mitigate: The material is used to make dental devices which work to temporarily replace or support part of the anatomy of the oral cavity.

COMPARISION WITH THE PREDICATE DEVICE

The Duracetal thermoplastic resin is substantially equivalent to the predicate, Duraflex thermoplastic resin. See table A. The devices share the same intended use and there are no new questions of safety and effectiveness.

Criteria	Duracetal results	Predicate results (Duraflex)	Comparison
indications for use	To be used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.	To be used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.	The indications for use are the same
Raw material	Thermoplastic dental resin	Thermoplastic dental resin	Both are the same
Sterility	Non-sterile	Non-sterile	Both are the same
Anatomical site	mouth	mouth	Both are the same
Single use	Not intended for singe use	Not intended for singe use	Both are the same
Re-processing	Not intended for re-processing	Not intended for re-processing	Both are the same
Rx use	yes	yes	Devices made from both resins are per a doctor's prescription / intervention.

Table A

Summary of the technological characteristics of Duracetal compared to the predicate device, Duraflex.

Both products are purchased by dental labs and are then used to make oral devices as per the direction of a doctor / dental practitioner.

The technology for the pellet form is the same. Both the Duracetal pellets and the Duraflex pellets are intended to be melted and injection-molded within a laboratory environment to form dental devices. However, the heating temperature and time is different. This is to accommodate an even flow of the molten Duracetal material.

Although both are from the same family of chemicals, the individual chemical composition is different. Biocompatibility results show that this difference does not affect safety and effectiveness.

The technology for the Duracetal disc is different. The disc is intended to be milled in a dental CNC machine to make the same devices.

The final devices, made from the Duracetal pellets, Duracetal discs or the predicate Duraflex pellets then go through the same steps. They are temporarily fitted on the patient by a doctor / dental practitioner.

PERFORMANCE DATA

The Duracetal thermoplastic resin was tested for conformance and / or developed in accordance with the following standards:

ISO 10993-1: Biological evaluation of medical devices

ISO 20795-1: Dentistry – base polymers- part 1: Denture base polymers

ASTM D792 Density

ASTM D638 Tensile Strength

ASTM D638 Tensile Modulus

ASTM D790 Flexural strength

ASTM D790 Flexural / Bending Modulus

ASTM D570 Water sorption

ASTM D256 Izod Impact, Notched

It is also conforming to ISO 13485: Medical devices- Quality management systems- requirements for regulatory purposes.

The specific biocompatibility tests conducted were:

- Cytotoxicity
- Sensitization
- Irritation –intracutaneous reactivity
- Subchronic toxicity

Results from the performance data (discussed above) demonstrated that the device is as safe, as effective, and performs as well as or better than the predicate device.

CONCLUSION

Based on the comparison of the Duracetal thermoplastic resin to the predicate Duraflex thermoplastic resin and based on the non-clinical testing, it is concluded that the Duracetal thermoplastic resin is substantially equivalent to the predicate device.