July 31, 2020

DK Mungyo Corporation
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt, STE 200
Irvine, California 92620

Re: K190790
Trade/Device Name: Flex Fit
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: April 20, 2020
Received: May 4, 2020

Dear Priscilla Chung:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

for Srinivas "Nandu" Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K190790

Device Name

FLEX FIT

Indications for Use *(Describe)*

This product is indicated for the manufacturing of bases of partial or full removable dentures, occlusal splints and night guards through heating and pneumatic injection of the material, following the Instructions of Use that come with the product.

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

(K190790)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: July 29, 2020

1. 510K Applicant / Submitter:

DK MUNGYO CORPORATION
248, Anha-ro, Hallim-myeon, Gimhae-si, Gyeongnam, 50852
Republic of KOREA
Phone: +82-055-905-2600

2. Submission Contact Person

LK Consulting Group USA, Inc.
1150 Roosevelt, STE 200, Irvine CA 92620
Priscilla Juhee Chung
Phone: 714.202.5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

- Proprietary Name: FLEX FIT
- Common Name: Dental Denture Resin
- Classification: Class II (21 CFR 872.3760)
- Classification Name: Denture Relining, Repairing, or Rebasing Resin
- Product Code: EBI

4. Predicate Device

- Primary Predicate Device:
  DEFLEX / K113608

- Reference Devices:
  - ACRYTONE, REZEN NF, AND ISO FAST DENTURE RESINS / K130680
  - TCS UNBREAKABLE / K053060
  - FLEXITE SUPREME, FLEXITE PLUS, FLEXITE M.P., NORTHERN AND FLEXITE PRO-GUARD / K072479

5. Description:

FLEX FIT is a polyamide resin for non-clasp dentures. It is suitable for deep undercut cases, which need strength. The resin material has an inherent flexibility allowing for a strong yet flexible denture to be created. FLEX FIT (known as Bio Tone in attached test summaries) is a denture resin that is primarily based on polyamide. It is sold as a clear or pink colored, fine granular resin that is 1~2 mm3 in diameter. The resin is packaged in a re-sealable plastic containers. Using an injection-molding method, FLEX FIT polyamide resin can be effectively used to make various types of dentures that retain the highly flexible, yet durable characteristics. It is a highly effective material for making non-clasp dentures, partial prosthetic dentures, dental plates, denture bases, bite plates, personal trays, night guards, splints, etc. It uses thermal polymerization as its mode of polymerization. The FLEX FIT offers two colors: clear and pink.

8. Indications for Use

This product is indicated for the manufacturing of bases of partial or full removable dentures, occlusal splints and night guards through heating and pneumatic injection of the material, following the Instructions of Use that come with the product.

9. Substantial Equivalence Discussion:

The indications for use of the subject device is the same as the predicate device and it uses the same material, Polyamide. Both the devices confirms to ISO 20795, substantially equivalent in performance. The only difference is that the predicate device offers five colors and the subject devices only offer two colors but this difference does not raise an issue in substantial equivalence as the pigment is only to achieve aesthetic effects on the manufactured denture. Since it is not related to performance, we believe this difference does not raise a question.

Device Name	FLEX FIT	DEFLEX
510k #	K190790	K113608
Manufacturer	DK MUNGYO CORPORATION	NUXEN S.R.L.
Product Code	EBI	EBI
Regulation	21 CFR§872.3760	21 CFR§872.3760
Common Name	Dental Denture Resin	Dental Denture Resin
Indications for Use	This product is indicated for the manufacturing of bases of partial or full removable dentures, occiusal splints and night guards through heating and pneumatic injection of the material, following the Instructions of Use that come with the product.	This product is indicated for the manufacturing of bases of partial or full removable dentures, occiusal splints and night guards through heating and pneumatic injection of the material, following the Instructions of Use that come with the product.

Material	Polyamide	Polyamide
Physical testing meets standard for dental base polymers	ISO 20795 - yes	ISO 20795 - yes
Biocompatibility	ISO 10993 complied	ISO 10993 complied
Device Appearance	Granule	Granule
Colors	2 shades including clear and pink	5 shades including clear and pink

10. Performance Tests (Non-clinical)

- Performance Tests in accordance with ISO 20795-1
- Biocompatibility Tests in accordance with ISO 10993
  - Cell Toxicity (Agar Layer Method) per ISO 10993 -5
  - Sensitization Test (LLNA, Polymer) per ISO 10993 - 10
  - Oral Mucosal Stimulation (Solidity Specimen) per ISO 10993 - 10
  - Acute Toxicity (Oral and Intraperitoneal Administration) per ISO 10993 -11

The test results of non-clinical tests performed on the subject device supported that it is substantially equivalent to the predicate devices despite the differences.

11. Conclusions:

Based on the information provided in this premarket notification, DK MUNGYO CORPORATION concludes that the FLEX FIT is substantially equivalent to the predicate device as described herein in.