May 3, 2019

Mavrik Dental Systems Ltd
℅ Sherwyn Davidson
QA/RA Director
25 Ha Haroshet Street 6th Fl.,
Raanana, 4365613
Israel

Re: K182118
Trade/Device Name: armor LC™
Regulation Number: 21 CFR 872.6300
Regulation Name: Rubber Dam And Accessories
Regulatory Class: Class I
Product Code: EIE
Dated: April 3, 2019
Received: April 3, 2019

Dear Sheila Hemeon-Heyer:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Malvina Eydelman, M.D.
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182118

Device Name
armor LC™

Indications for Use *(Describe)*

armor LC™ is a resin-based, light-cured protective barrier material recommended to protect dental materials or tissues.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Mavrik Dental Systems Ltd.'s armor LC™ Device

Applicant's name: Mavrik Dental Systems Ltd.

Contact Person: Sherwyn Davidson
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Date Prepared: April 30, 2019

Name of Device: armor LC™

Common or Usual Name: Rubber dam and accessories

Classification:

Product Code:	EIE
Regulation No:	21 C.F.R. §872.6300
Class:	Class: I
Classification Panel:	Dental

Predicate Device: Primary predicate: Triumph Resin Dam (K151945)
Reference predicate: OpalDam (K971284)

Intended Use / Indications for Use

armor LC™ is a resin-based, light-cured protective barrier material recommended to protect dental materials or tissues.

Device Description

armor LC™ is a light-cured resin dam designed to seal around and protect the gingival tissue during professional dental procedures. It consists of a viscous urethane dimethacrylate (UDMA)-based resin foam supplied in a black 1 mL syringe. armor LC™ is only for prescription use and is a single-use, non-sterile, product. Using an applicator tip, the uncured product is applied over the gingival margin where it flows to form a seal at the base of the teeth. It is then rapidly light cured in situ to form a flexible material barrier. After the dental procedure it is readily removable with simple dental instruments.

Substantial Equivalence

The following table provides a comparison of the armor LC™ to the primary and reference predicate devices:

	armor LC™ device (K182118)	**Primary Predicate Triumph Resin Dam (K151945)**	**Reference Predicate: OpalDam (K971284)**
Device Class	Class I	Class I	Class I
Classification Panel	Dental	Dental	Dental
Product Code	EIE	EIE	EIG
Regulation Description	Rubber dam and accessories	Rubber dam and accessories	Dental hand instrument
Regulation number	21 C.F.R. §872.6300	21 C.F.R. §872.6300	21 CFR 872.4565
Indications for Use	armor LC™ is a resin-based, light-cured protective barrier material recommended to protect dental materials or tissues.	Triumph Resin Dam is a resin-based, light-cured protective barrier material recommended to protect dental materials or tissues.	OpalDam resin is used to protect soft tissue adjacent to the teeth during in-office bleaching. OpalDam is used with Opalescence Xtra (35% hydrogen peroxide) “power” bleaching agent.
Device Type	Light cured rubber dam	Light cured rubber dam	Light-cured rubber dam
Composition	Urethane dimethacrylate, cetyl alcohol, light curing chemistry, flavor	Urethane acrylates, light-curing chemistry, silica, titanium dioxide	Diurethane dimethacrylate, cetyl alcohol, light-curing chemistry, titanium dioxide
Light Cure Capabilities:	Yes	Yes	Yes
Light Cure Setting Time:	<20 seconds	<20 seconds	<20 seconds
Flexibility to allow removal in one piece, when applied around a dental tooth model	Yes	Yes	Yes
Biocompatible	Yes	Yes	Yes
Sterilization	Non-sterile Not intended to be sterilized by end-user	Non-sterile Not intended to be sterilized by end-user	Non-sterile Not intended to be sterilized by end-user

Substantial Equivalence Discussion:

armor LC™ device has the same indications for use statement as the primary predicate device, Triumph Resin Dam, which was found to be substantially equivalent to the reference predicate device, OpalDam. The only technological difference between armor LC™ and the two named predicate devices is minor differences in their chemistry. All three products include acrylates as the base monomer, light curing chemistry for polymerization, and fillers to achieve the desired mechanical properties. While the exact chemical compositions of the predicate devices is unknown, the main difference appears to be that armor LC™ does not include titanium dioxide, which is added to some resins as a filler or pigment. armor LC™ also includes a rum flavor ingredient, which has no impact on the device properties. Side-by-side bench testing comparing armor LC™ to the predicate devices demonstrated substantial equivalence of the handling and technical characteristics.

Non-Clinical Performance Data

Bench Performance Testing

Mavrik Dental Systems conducted several performance tests to demonstrate that armor LC™ device complies with performance standards and that it functions as intended. Bench performance tests included:

- Appearance and handling
- Removal in one piece
- Curing temperature
- Sensitivity to ambient light
- Viscosity
- Depth of cure
- Flexural strength

In all instances, armor LC™ device functioned as intended and met the pre-defined acceptance criteria.

Biocompatibility

armor LC™ is a surface contact device in limited contact with mucosal membranes. The testing required by FDA and ISO 10993-1:2009 “Biological Evaluation of Medical Devices - Part 1: Evaluation and testing Within A Risk Management Process” are cytotoxicity, irritation, and skin sensitization. Testing was conducted on the final, finished armor LC™ device in accordance with the international recognized consensus standards listed below and was found to be biocompatible.

- ISO 10993-1 Fourth edition 2009-10-15, Biological evaluation of medical devices
- ISO 10993-5 Third edition 2009-06-01, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
    - Uncured material – Direct contact method with exposure of 5 minutes. The material must be cured within 1 minute of application in clinical use.

    - Cured material – ISO elution method with exposure of 48 hours
- ISO 10993-10 Third Edition 2010-08-01, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
    - Uncured material - 4 hours
    - Cured material - 7 days
- ISO 7405 Second edition 2008-12-15, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry [Including: Amendment 1 (2013)]

Conclusion

The armor LC™ device is substantially equivalent to the predicate device in design, composition, principle of operation, biocompatibility, performance, and intended use.