October 15, 2020

Centrix Incorporated
% Roger Mastrony
President
MedTek LLC
2516 Kettle Creek Court
Lincolnton, North Carolina 28092

Re: K200764
Trade/Device Name: Statstix
Regulatory Class: Unclassified
Product Code: MVL
Dated: March 20, 2020
Received: March 24, 2020

Dear Roger Mastrony:

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

Indications for Use

510(k) Number (if known): K200764

Device Name: ***StatStix***

Indications for Use:

StatStix is applied to control temporary bleeding caused by minor cuts and abrasions that may occur on gingival tissue during dental procedures.

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Prescription Use _X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

centrix
Making Dentistry Easier.℠

510(k) SUMMARY

Premarket Notification Number K200764

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

510(k) Sponsor:
Centrix Incorporated
770 River Road
Shelton, CT. 06484
800.235.5862

Submitted by:
Roger Mastrony
MedTek LLC
2516 Kettle Creek Court
Lincolnton, N.C. 28092
203.640.5047

Date of Submission: March 20, 2020

Trade Name: StatStix
Common Name: Cord, Retraction
Product Code: MVL
Device Class: Unclassified

Devices for Which Substantial Equivalence is Claimed:

- **Primary-Vista Clear, K193389 Unclassified, Product Code MVL, Vista Dental Products**
- **Reference Device- BendaWedge, K140144 Class 1 Medical Devices, Product Code EJB, Centrix Incorporated**

Summary:

Device Description

StatStix is designed incorporating a hand-held polypropylene handle with a nylon polyamide applicator tip coated with a dried solution of 25% Aluminum Sulfate Hydrate Solution with Mint Flavor. The device is configured in two sizes to help control minor gingival bleeding intended for transient use by a dentist during dental restorative procedures.

Indications for Use:

StatStix is applied to control temporary bleeding caused by minor cuts and abrasions that may occur on gingival tissue during dental procedures

Comparative Indications for Use Chart:

Device	Category	Indications for Use
StatStix	Subject device	StatStix is applied to control temporary bleeding caused by minor cuts and abrasions that may occur on gingival tissue during dental procedures
Vista Clear	Primary device	Vista Clear is intended for sulcus retraction prior to impression-making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord.
Benda Wedge	Reference device	Benda Wedge is an inter-proximal wedge coated with an astringent to be used in combination with other devices to temporarily retain composite or amalgam restorative material as well as to control gingival bleeding during dental restorations.

Technological Characteristics Comparison:

Primary Predicate Vista Clear K193389	StatStix K200764
Contains 26.6% of an Aluminum Chloride Astringent	Coated with dried 25% Aluminum Sulfate astringent Solution with Mint flavor
Intended for sulcus retraction prior to impression taking and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord. Facilitates the insertion of a cord into the sulcus	Substantially Equivalent in that Indicated to Control Minor Gingival Bleeding during dental procedures
Mode of Operation is to Mechanically Desiccate Gingival Tissue with the addition of Mechanical Pressure in conjunction with cord	Substantially Equivalent in that placement of the wetted StatStix applicator results in tissue constriction at intended site and subsequent hemostasis

Used in combination with other devices to temporarily retain composite or amalgam restorative material during dental restorations	**No Equivalency Claimed**

Non Clinical Performance Data:
Biocompatibility testing was performed in accordance with ISO 10993-1 guidelines; specifically, biocompatibility testing was performed for cytotoxicity per ISO 10993-5 and sensitization/irritation per ISO 10993-10.

Physical property testing consisted of FTIR, pH and dosage weight evaluations and was performed according to standard laboratory benchtop practices.

Shelf-Life Testing
Shelf-life testing was performed consistent with ASTM F1980 and the obtained results allow for a two-year expiration dating of this device

Clinical Testing
Clinical testing has not been performed on this product

Conclusion
We believe given the StatStix device is substantially equivalent to the primary device referenced in this submission.