July 10, 2023

Lumendo AG
Mark Bispinghoff
Coo
Chemin du Closel 5
Renens, VD 1020
SWITZERLAND

Re: K231387
Trade/Device Name: Endofill
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: May 12, 2023
Received: May 12, 2023

Dear Mark Bispinghoff:

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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231387

Device Name

Endofill (1)

Indications for Use *(Describe)*

Endofill (1) is indicated for the permanent obturation of root canals following root canal treatment

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) #:

510(k) Summary

Prepared on: 2023-06-27

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Lumendo AG
Applicant Address	Chemin du Closel 5 Renens VD 1020 Switzerland
Applicant Contact Telephone	+41445896802
Applicant Contact	Dr. Mark Bispinghoff
Applicant Contact Email	mark.bispinghoff@lumendo.ch

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Endofill (1)
Common Name	Root canal filling resin
Classification Name	Resin, Root Canal Filling
Regulation Number	872.3820
Product Code	KIF

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K211995	Sonendo Filling Material 5C	KIF
K071106	EndoREZ Dual Cure	KIF

Device Description Summary

21 CFR 807.92(a)(4)

Endofill is a hydrophilic, radiopaque material intended for permanent obturation of the root canals following root canal treatment. It consists of a liquid, flowable material that is injected into the prepared and cleaned root canal and converted into a solid polymer by photocuring. The cured material remains within the root canal to obturate (seal) it.

Endofill is provided ready-to-use in single-use plastic syringes which are sealed inside aluminum-laminate pouches.

The Endofill material is the only part of the device that directly contacts the tissue. The syringe in which the material is provided comes in contact with Endofill material, so it contacts the tissue indirectly.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Endofill is indicated for the permanent obturation of root canals following root canal treatment

Indications for Use Comparison

21 CFR 807.92(a)(5)

Endofill and the primary predicate device share an identical Indications for Use statement indicating the products are used for permanent obturation of the root canal following root canal treatment. The additional predicate device's Indications for Use statement lists specific modes of application and includes a statement that is may be used with all conventional endodontic obturation techniques.

Because the additional predicate may be used with all conventional endodontic obturation techniques, it shares the same intended use with Endofill and the primary predicate device (permanent obturation of the root canal following root canal treatment). Therefore, although the Indications for Use language differs between Endofill and the additional predicate device, these differences are not critical to the intended use of the device and do not affect the safety and effectiveness of the device when used as labeled.

Technological Comparison

21 CFR 807.92(a)(6)

Endofill has the same technological characteristics when compared to the primary and additional predicate device with regards to type of use, target users, material characteristics, principle of operation, mechanism of action, treatment site, sterility, delivery form, packaging, and material compatibility.

Minor differences in the basic chemical composition, curing mechanism, and material properties tested were determined not to raise different questions of safety or effectiveness. The subject and the primary predicate device both form a crosslinked, insoluble hydrogel polymer upon curing and are composed of a cross-linkable compound, a solvent, a radiopacifier, and an initiator.

Endofill complies with the performance requirements set out in ISO6876:2012 and the biocompatibility requirements of ISO10993-1:2018 and ISO7405:2018. Therefore, despite some differences in the basic chemical composition, performance, and safety (biocompatibility), test results support that the subject device is substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical bench performance testing was conducted to provide evidence that the physical-chemical properties of Endofill are substantially equivalent to the predicate devices and to support safety and performance of the device for its intended use.

The FDA-recognized consensus standard 4-199 (ISO 6876:2012) specifies the requirements and test methods for root canal (endodontic) sealing materials. Accordingly, flow, film thickness, solubility & disintegration, and radiopacity have been measured.