September 24, 2025

Kulzer, LLC
Lucas Harmon
Quality and Regulatory Engineer
4315 S Lafayette Blvd
South Bend, Indiana 46614

Re: K243910
Trade/Device Name: Retraxil
Regulatory Class: Unclassified
Product Code: MVL,
Dated: August 25, 2025
Received: August 25, 2025

Dear Lucas Harmon:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243910

Device Name

Retraxil blue

Indications for Use *(Describe)*

For the temporary displacement of the marginal gingiva and drying of the gingival sulcus, e.g. for
• conventional or digital impressions,
• cementation of temporary and permanent restorations
• and the creation of Class II and V fillings.

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.

510(k) #: K243910

510(k) Summary

Prepared on: 2025-08-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Kulzer, LLC
Applicant Address	4315 S Lafayette Blvd South Bend IN 46614 United States
Applicant Contact Telephone	(574) 299-5402
Applicant Contact	Mr. Lucas Harmon
Applicant Contact Email	Lucas.Harmon@kulzer-dental.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Retraxil blue
Common Name	Unclassified
Classification Name	Cord, Retraction
Regulation Number	Unclassified
Product Code(s)	MVL

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K050180	Expasyl	MVL
K092384	LiquiCord	MVL

Device Description Summary

21 CFR 807.92(a)(4)

RetraXil belongs to the group of dental retraction material, mainly as cords (threads) with astringent agents. The retraction material is also marketed in form of a paste as alternative to the cords. RetraXil is a retraction paste containing aluminium chloride as astringent agent, which serves as hemostatic agent.
RetraXil is marketed as a gingival retraction paste with no hints of performance or safety issues for patients and users.

Retraxil is a retraction paste stored in a 1g syringe with a cannula and twisting aid.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

For the temporary displacement of the marginal gingiva and drying of the gingival sulcus, e.g. for
• conventional or digital impressions,
• cementation of temporary and permanent restorations
• and the creation of Class II and V fillings.

Indications for Use Comparison

21 CFR 807.92(a)(5)

RetraXil, Expasyl, and LiquiCord are all intended for temporary marginal gingival retraction and drying of gingival sulcus and therefore have the same indication for use and similar Indications. While Expasyl (primary predicate device) is delivered in the form of a PLT, RetraXil and LiquiCord (reference device) are both delivered via a syringe. Please find detailed information of the similarities and

differences in products in the below Attachment "Substantial Equivalence Comparison Table" as well as in Attachment "Retraxil Equivalence Report_V02_17022021".

Technological Comparison

21 CFR 807.92(a)(6)

Expasyl (Acteon) contain Aluminum salts, mostly Aluminum Chloride in the same concentration as RetraXil has.
Out of the information of ingredients made publicly available, Expasyl has nearly the same composition as RetraXil with 15% Aluminium chloride as astringent and Kaolin as matrix material. Therefore RetraXil and Expasyl can be considered as equivalent respective to their composition.
The consistency of Retraxil is lower compared to the consistency to Expasyl due to the use of a Syringe instead of an PLT, which allows to press out material with higher consistency. Comparatively, LiquiCord utilizes a Syringe in a similar manner to RetraXil.
The physical effects of RetraXil and Expasyl can be considered equivalent.
Considering composition, bench testing, and shelf life data, RetraXil is assessed to Expasyl, which have very similar compositions and performance.
More information can be found in the below Attachment "Substantial Equivalence Comparison Table" as well as in Attachment "Retraxil Equivalence Report_V02_17022021".

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Retraxil mechanical and thermal testing was performed and described as well in the chapter above.
The tests can be found in the following attachments:
- Shelf life report ("Bench Testing_Shelf Life Report Retraxil_Thermal Safety_04.08.2020")
- CoAs
- Usability Tests ("Bench Testing_Test protocol_PA_REPA-RetraXil_LOT K010030_20210225")
- Design and development documents ("Bench Testing_Functional Specifications_Fulfillments_03122019")

The clinical evaluation for Retraxil is based on currently available scientific literature, survey among users and PMS data held by the manufacturer. The specific questions of this clinical evaluation were answered with adequate and suitable clinical data from the literature. Therefor a clinical investigation with the device in question is not necessary and the route for this clinical evaluation is literature based.
The clinical evidence demonstrates that residual risks identified are acceptable when weighed against the benefits for the patient. The benefit-risk ratio is evaluated as positive.
The adequate safety and performance of the medical use of the evaluated medical device was confirmed within this critical evaluation with clinical data from product surveillance and from scientific literature.

Please see explanation above.