June 10, 2025

Fomed Industries, Inc.
% Kiwi Xu
Official Correspondent
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Building, 1500# Century Ave
Shanghai,
CHINA

Re: K250735
Trade/Device Name: Dental Barrier and Sleeves
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape And Drape Accessories
Regulatory Class: Class II
Product Code: PEM
Dated: May 15, 2025
Received: May 15, 2025

Dear Kiwi Xu:

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 Adjodha, MChE, RAC, CQIA
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
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250735

Please provide the device trade name(s).

Dental Barrier and Sleeves

Please provide your Indications for Use below.

Dental Barrier and Sleeves are intended to be used as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #:K250735

510(k) Summary

Prepared on: 2025-03-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	FOMED INDUSTRIES INC.
Applicant Address	20 Han sha Road HouHu District 433115 Qian Jing City, Hubei Province P.R. China. Qianjing China
Applicant Contact Telephone	+86 13869469536
Applicant Contact	Mr. Xing He
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Correspondent Address	14th Floor, Dongfang Building, 1500# Century Ave. Shanghai China
Correspondent Contact Telephone	+86-21-58817802
Correspondent Contact	Ms. Kiwi Xu
Correspondent Contact Email	weijia.xu@sungoglobal.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Dental Barrier and Sleeves
Common Name	Surgical drape and drape accessories
Classification Name	Dental Barriers And Sleeves
Regulation Number	878.4370
Product Code(s)	PEM

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K190484	BH Medical Dental Barrier Sleeves and Barrier Film	PEM

Device Description Summary

21 CFR 807.92(a)(4)

Dental Barrier and Sleeves consist of various sizes and shapes of polyethylene covers which are positioned on various small hand-held dental instruments such as hand pieces, curing lights, air/water syringes and similar hand instruments. In other forms, they are used to cover various devices such as dental chairs, dental instrument trays, x-ray heads, and others. The products are sold non-sterile, prepackaged, and are disposable, single use only.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Dental Barrier and Sleeves are intended to be used as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Dental Barrier and Sleeves are intended to be used as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only.

Technological Comparison 21 CFR 807.92(a)(6)

The subject and predicate devices have the same intended use. Both are single-use devices, and material and performance characteristic are identical. The minor differences in specifications and tolerances between the subject and predicate devices do not raise questions of safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance test including resistance to penetration, tear resistance, tensile strength, and puncture resistance was performed in accordance with ASTM F1670, ASTM F1671, ASTM D882, ASTM F1342 and ASTM D1004.

Not Applicable.

This proposed device and the predicated products have same intend use, principles of operation, material composition, sterility, biocompatibility, performance properties and performance testing items. And their specifications and tolerances are very similar. To ensure all the key characteristic of the products can meet the requirements, the testing was done and all the results indicate the positive conclusion.

Based on the analysis above, we confirm these devices are essentially equivalent.