August 3, 2021

Minitube AB
% Vaibhav Arvind Rajal
Official Correspondent for Minitube AB
MDI Consultants Inc.
55 Northen Blvd. Suite 200
Great Neck, New York 11021

Re: K211026
Trade/Device Name: Minitube Dentasleeve Protective Barrier Sleeves
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: Class II
Product Code: PEM
Dated: May 17, 2021
Received: May 21, 2021

Dear Vaibhav Arvind Rajal:

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, 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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211026

Device Name
Minitube Dentasleeve Protective Barrier Sleeves

Indications for Use *(Describe)*
Minitube Dentasleeve Protective Barrier Sleeves are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only.

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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K211026

510(k) Summary

The assigned 510(k) number is

1. Submitter's Identification:

Minitube AB
Byvagen 44, 835 96 Trangsviken
Sweden

Date: March 29, 2021

Contact: Mr. Bengt Myhrman
President, Minitube AB
Minitube AB
Byvagen 44, 835 96 Trangsviken
Sweden
Email: bengt@minitube.se

2. Name of the Device:

Trade Name:	Minitube Dentasleeve Protective Barrier Sleeves
Common Name:	Dental Barriers and Sleeves
Regulation Description:	Surgical drape and drape accessories.
Product Code:	PEM
Regulation Number:	878.4370
Device Class:	II

3. Information on Predicate Devices:

Predicate Device:

Trade/Device Name:	Barrier Sleeves
Regulation Number:	21 CFR 878.4370
Regulation Name:	Surgical drape and drape accessories.
Regulatory Class:	Class II
Product Code:	PEM

4. Indications for Use Statement:

Minitube Dentasleeve Protective Barrier Sleeves are intended to serve as a disposable barrier for dental instruments and equipment. This device is nonsterile and intended for single patient use only.

5. Device Description:

Minitube Dentasleeve Protective Barrier Sleeves are made of polyethylene film and are used as accessories to dental instruments and equipment used during dental procedures. These disposable barrier sleeves are offered in various shapes and sizes to fit over and cover the intended dental instruments and equipment. The disposable Barrier Sleeves slip over the ends of the respective devices, allowing for the attachment of those parts of the devices used during dental procedures. Barrier Sleeves act as a physical barrier, augmenting existing infection control techniques, and facilitate clean up. The Minitube Dentasleeve Protective Barrier Sleeves are available in below sizes. All sizes below are provided in millimeters (mm, approx.) and excluding paper liner, i.e. actual sleeve only:

- **1 ml**
  Width: 29 mm
  Length: 148 mm

- **5 ml**
  Width: 43 mm
  Length: 195 mm

- **50ml**
  Width: 63 mm
  Length: 126 mm

6. Substantial Equivalence Comparison Chart between Subject device and the Predicate devices:

The subject Minitube Dentasleeve Protective Barrier Sleeves is substantially equivalent to Barrier Sleeves device, K191448

Item description	**Minitube Dentasleeve Protective Barrier Sleeves Subject Device**	**Barrier Sleeve K#191448 Predicate Device**	**Substantially Equivalent or Different**
Indications for Use Statement	Minitube Dentasleeve Protective Barrier Sleeves are intended to serve as a disposable barrier for dental instruments and equipment. This device is nonsterile and intended for single patient use only.	Barrier Sleeves are intended to serve as a disposable barrier for dental instruments and equipment. This device is nonsterile and intended for single patient use only.	SE
Precaution Measures/Contraindications	None	None	SE
Summary of Indications	**The indications and contraindications for the predicate and the new device are the same.**		
Working principle	Minitube Dentasleeve Protective Barrier Sleeves are made of polyethylene film and are used as accessories to dental instruments and equipment used during dental procedures. These disposable barrier sleeves are offered in various shapes and sizes	Disposable Barrier Sleeves are made of polyethylene film and are used as accessories to dental instruments and equipment used during dental procedures. These disposable barrier sleeves are offered in	SE

	to fit over and cover the intended dental instruments and equipment. The Minitube Dentasleeve Protective Barrier Sleeves slip over the ends of the respective devices, allowing for the attachment of those parts of the devices used during dental procedures. Minitube Dentasleeve Protective Barrier Sleeves act as a physical barrier, augmenting existing infection control techniques, and facilitate clean-up.	various shapes and sizes to fit over and cover the intended dental instruments and equipment. The Disposable Barrier Sleeves slip over the ends of the respective de-vices, allowing for the attachment of those parts of the devices used during dental procedures. Disposable Barrier Sleeves act as a physical barrier, augmenting existing infection control techniques, and facilitate clean-up.	
Delivery forms/dosage	There are several sleeves for dental instruments and equipment.	There are several sleeves for dental instruments and equipment.	SE Minitube Dentasleeve Protective Barrier Sleeves are supposed to be 3 articles, which differ in size of the

			sleeve. These will fit perfectly over a 1ml, 5ml and 50ml syringe, respectively.
Shelf life	5 years	5 years	SE
Principles of operation	The disposable barrier sleeves and covers fit over and cover the intended dental instruments and equipment.	The disposable barrier sleeves and covers fit over and cover the intended dental instruments and equipment.	SE
Material	Polyethylene film	Polyethylene film	SE
Material composition	Low density polyethylene film	Low density polyethylene film	SE The material in the Predicate device and the new device are identical.
Summary of Material Composition	**No difference. The same supplier (Minitube AB, Sweden) manufactures the predicate and the subjec devices. Both the devices made of the identical material.**		
Dimensions	Size 1: 29 * 148 mm Size 2: 43 * 195 mm Size 3: 63 * 126 mm	Size 1: 29 * 148 mm Size 2: 36 * 279 mm	SE
Film Thickness	0.03 mm	0.03 mm	SE

			The material in the Predicate device and the new device are identical.
Shape	Custom design to fit the intended dental instruments and equipment they cover	Custom design to fit the intended dental instruments and equipment they cover	SE
Dimensions	Determined by the size and shape of the dental instruments and equipment they cover	Determined by the size and shape of the dental instruments and equipment they cover	SE
Color	Clear	Clear	SE
Paper backing (y/n)	Yes	Yes	SE
Single use (Y/N)	Yes	Yes	SE
Sterility	n/a	N/a	The product is non-sterile
Synthetic Blood Penetration test (ASTM F1670)	Pass	Pass	SE
Synthetic Blood Penetration at seams and non-continuou components ASTM F1670/F1670M	Pass	Pass	SE
Viral Penetration test (ASTM F1671)	Pass	Pass	SE

Viral penetration at seams and non- continuous components ASTM F1671/F1671M	Pass	Pass	SE
Performance Testing Summary	**No difference. The same supplier (Minitube AB, Sweden) manufactures the predicate and the subject devices. Both the devices made of the identical material. The results of Performance testing are included in this submission.**		
Biocompatibility: Cytotoxicity – ISO10993-5 Sensitization – ISO10993-10	Non-cytototoxic Non-sensitizing, non-irritating	Non-cytototoxic Non-sensitizing, non-irritating	SE SE The material in the Predicate device and the new device are identical.
Summary of Biocompatibility	**No difference. The same supplier (Minitube AB, Sweden) manufactures the predicate and the subjec devices. Both the devices made of the identical material. The results of Biocompatibility testing are included in this submission.**		
Tensile strength ASTM D882	0.03 mm – acceptable	0.03 mm – acceptable	SE
Puncture Resistance ASTM F1342/F1342M	0.03 mm – acceptable	0.03 mm – acceptable	SE
Tear Resistance ASTM D1004	0.03 mm – acceptable	0.03 mm – acceptable	SE
Mechanical Properties Summary	**No difference. The same supplier (Minitube AB, Sweden) manufactures the predicate and the subject devices. Both the devices made of the identical material. The results of Mechanical properties testing are included in this submission**		

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Performance testing was provided in support of the substantial equivalence determination and to validate and verify that the subject device met all of the requirements of related international standards. Results of these tests demonstrate compliance with the requirements of the consensus standards.

The ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, is not applicable for the subject device, as the subject device does not come in direct contact with the tissue. The following biocompatibility testing have been conducted on the subject device:

- ISO 10993-5: Invitro Cytotoxicity: Cytotoxicity Study Using the ISO Elution Method
- ISO 10993-10: Irritation and Skin Sensitization: ISO Guinea Pig Maximization Sensitization Test – Extract
- ISO 10993-10: Irritation and Skin Sensitization: ISO Intracutaneous Study in Rabbits
- ISO 10993-11: Systemic Toxicity: ISO Systemic Toxicity Study in Mice - Extract

The performance of the proposed subject device, Minitube Dentasleeve Protective Barrier Sleeves, met the requirements of the biocompatibility testing conducted to support substantial equivalence with the predicate, Barrier Sleeves, K191448.

The performance testing (Bench) of the subject device, Minitube Dentasleeve Protective Barrier Sleeves, met the requirements of the non-clinical bench testing conducted to support substantial equivalence with the predicate, Barrier Sleeves (K191448). Below is a summary of the testing performed:

- ASTM F1670/F1670M Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood
- ASTM F1671/ F1671M Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

Mechanical Property	Standard	Proposed Subject Device Minitube Dentasleeve Protective Barrier Sleeves	Predicate Device Barrier Sleeves K191448
Tensile strengt	ASTM D882	0.03mm – Identical to Predicate Device	FDA 510(k) cleared with 0.03mm result.
Puncture Resistance	ASTM F1342/F1342M	0.03mm – Identical to Predicate Device	FDA 510(k) cleared with 0.03mm result.
Tear Resistance	ASTM D1004	0.03mm – Identical to Predicate Device	FDA 510(k) cleared with 0.03mm result.

Below is a summary of the mechanical properties testing performed on the proposed subject Minitube Dentasleeve Protective Barrier Sleeves device:

- ASTM D882 Standard Test Methods for Tensile Properties of Thin Plastic Sheeting
- ASTM F1342/ F1342M Standard Test Method for Protective Clothing Material Resistance to Puncture
- ASTM D1004 Standard Test Method for Tear Resistance (Graves Tear) of Plastic Film and Sheeting

The results of the mechanical properties testing for the samples of the proposed devices, Barrier Sleeves, is identical to those reported for the predicate device, Barrier Sleeves, K191448. The results indicate the subject device passed performance testing under the conditions of the tests, and supports the substantial equivalence of the subject device, Minitube Dentasleeve Protective Barrier Sleeves to its predicate device, Barrier Sleeves K191448.

8. Product Shelf Life

The Shelf life for the predicate device is 5 years. The claimed shelf life for the new proposed subject device is also 5 years, which is identical to the predicate device.

9. Conclusion:

Based on the substantial equivalence chart and the non-clinical performance testing data the subject device was demonstrated to be as safe, as effective and substantially equivalent to the predicate device.