October 8, 2019

Ivoclar Vivadent, AG
% Lori Aleshin
Director of Quality & Regulatory Affairs
Ivoclar Vivadent, Inc.
175 Pineview Drive
Amherst, New York 14228

Re: K191448
   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
   Dated: June 26, 2019
   Received: July 10, 2019

Dear Lori Aleshin:

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/comparison-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.


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
for Srinivas Nandkumar, Ph.D.
Acting 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

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)

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Submitter Information:
Lori Aleshin, Director of Quality and Regulatory Affairs
Ivoclar Vivadent, Inc.
175 Pineview Drive
Amherst, New York 14228
716-264-2045
lori.aleshin@ivoclarvivadent.com

Company: Ivoclar Vivadent, AG
Bendererstrasse 2, Schaan, FL-9494, Liechtenstein
+423-235-3535

Date Prepared: October 7, 2019

Device Name:
- Proprietary Name: Barrier Sleeves
- Classification Name: Surgical Drape and Drape Accessories
- CFR Number: (878.4370)
- Device Class: II
- Product Code: PEM

Predicate Device: Disposable Barrier Sleeves and Covers (K160232) by DENTSPLY International Inc.

Device Description: 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.

Indications for Use: 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.

Comparison to Predicate:

<table>
<thead>
<tr>
<th>Intended Use</th>
<th>Predicate device</th>
<th>Barrier Sleeves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
<td>Disposable Barrier Sleeves and Covers 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.</td>
<td>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.</td>
</tr>
<tr>
<td>Precaution Measures/</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Contraindications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of Indications</td>
<td>The indications and contraindications for the predicate and the new device are the same.</td>
<td></td>
</tr>
</tbody>
</table>
**Summary Principles of operation**

The working principle for both groups of devices is the same: the disposable barrier sleeves are placed over the devices. The form fits over the intended devices. The working principle is equivalent.

**Delivery forms/dosage**

There are several sleeves and covers for dental instruments and equipment.

**Summary of Delivery form content**

In the Clearance letter K160232 several sleeves and covers are listed. For the new devices (Bluephase Sleeves and Vivapen Sleeves) there are supposed to be 2 articles, which differ in the size of the sleeve. The sleeves perfectly fit over Ivoclar Vivadent’s curing lights (Bluephase) and Vivapen (applicator for liquids).

**Shelf life**

Supplier report is 5 years

**Summary of shelf life**

Shelf life for the predicate is not known. The claimed shelf life for the new devices (Bluephase and Vivapen Sleeves) is 5 years as recommended by the manufacturer of the sleeves. Storage Stability report was provided.

**Principles of operation**

The disposable barrier sleeves and covers fit over and cover the intended dental instruments and equipment.
### Summary of Operation

The principle of operation is the same.

### Material Composition

<table>
<thead>
<tr>
<th></th>
<th>Predicate device</th>
<th>Barrier Sleeves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material</td>
<td>Polyethylene film</td>
<td>Polyethylene film</td>
</tr>
<tr>
<td>Material composition</td>
<td>Low density polyethylene film</td>
<td>Low density polyethylene film</td>
</tr>
</tbody>
</table>

### Summary of Material Composition

No difference. The predicate and the new device are manufactured by the same supplier (Minitube AB, Sweden) and made of the same material.

### Biocompatibility

<table>
<thead>
<tr>
<th></th>
<th>Predicate device</th>
<th>Barrier Sleeves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytotoxicity – ISO 10993-5</td>
<td>Non-cytotoxic</td>
<td>Non-cytotoxic</td>
</tr>
<tr>
<td>Sensitization/Irritation – ISO 10993-10</td>
<td>Non-sensitizing, non-irritating</td>
<td>Non-sensitizing, non-irritating</td>
</tr>
</tbody>
</table>

### Summary of Biocompatibility

No difference. The predicate and the new device are manufactured by the same supplier (Minitube AB, Sweden) and made of the same material. The results of Biocompatibility testing are included in this submission.

### Performance Properties

<table>
<thead>
<tr>
<th></th>
<th>Predicate device</th>
<th>Barrier Sleeves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synthetic Blood Penetration ASTM F1670/F1670M</td>
<td>Pass</td>
<td>Pass</td>
</tr>
<tr>
<td>Synthetic Blood Penetration at seams and non-continuous components ASTM F1670/F1670M</td>
<td>Pass</td>
<td>Pass</td>
</tr>
<tr>
<td>Viral penetration ASTM F1671/F1671M</td>
<td>Pass</td>
<td>Pass</td>
</tr>
<tr>
<td>Viral penetration at seams and non-continuous components ASTM F1671/F1671M</td>
<td>Pass</td>
<td>Pass</td>
</tr>
</tbody>
</table>

### Summary

No difference. The predicate and the new device are manufactured by the same supplier (Minitube AB, Sweden) and made of the same material. The results of Performance testing are included in this submission.

### Mechanical Properties

<table>
<thead>
<tr>
<th></th>
<th>Predicate device</th>
<th>Barrier Sleeves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tensile strength ASTM D882</td>
<td>0.03 mm – acceptable</td>
<td>0.03 mm - acceptable</td>
</tr>
<tr>
<td>Puncture Resistance ASTM F1342/F1342M</td>
<td>0.03 mm – acceptable</td>
<td>0.03 mm - acceptable</td>
</tr>
<tr>
<td>Tear Resistance ASTM D1004</td>
<td>0.03 mm – acceptable</td>
<td>0.03 mm - acceptable</td>
</tr>
<tr>
<td>----------------------------</td>
<td>----------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td><strong>Summary</strong></td>
<td>No difference. The predicate and the new device are manufactured by the same supplier (Minitube AB, Sweden) and made of the same material. The results of Mechanical Properties testing are included in this submission.</td>
<td></td>
</tr>
<tr>
<td><strong>Device Characteristics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Predicate device</strong></td>
<td></td>
<td><strong>Barrier Sleeves</strong></td>
</tr>
<tr>
<td>Thickness</td>
<td>0.03 mm (Minitube AB, Sweden)</td>
<td>0.03 mm (Minitube AB, Sweden)</td>
</tr>
<tr>
<td>Shape</td>
<td>Custom design to fit the intended dental instruments and equipment they cover</td>
<td>Custom design to fit the intended dental instruments and equipment they cover</td>
</tr>
<tr>
<td>Dimensions</td>
<td>Determined by the size and shape of the dental instruments and equipment they cover</td>
<td>Determined by the size and shape of the dental instruments and equipment they cover</td>
</tr>
<tr>
<td>Color</td>
<td>clear</td>
<td>clear</td>
</tr>
<tr>
<td>Sterile</td>
<td>Not sterile</td>
<td>Not sterile</td>
</tr>
<tr>
<td>Single Use</td>
<td>Single use device</td>
<td>Single use device</td>
</tr>
<tr>
<td><strong>Summary</strong></td>
<td>The new and the predicate devices are made of the same material by the same supplier (Minitube AB, Sweden). Both devices are not sterile, for single use and differ only in the shape and the dimensions as the need to fit over different types of devices.</td>
<td></td>
</tr>
</tbody>
</table>

**Infection Control:**
The device is sold in a non-sterile condition.

**Non-Clinical Performance Data:**
The sponsor provided biocompatibility testing for the subject device. Direct contact with tissue is not intended. Therefore ISO 10993-1 is not applicable. Biocompatibility testing included Cytotoxicity study using the ISO Elution Method ISO 10993-5, the ISO 10993-10 Guinea Pig Maximization Sensitization Test and the ISO 10993-10 Intracutaneous Study in Rabbits-Irritation test. A Toxicological statement was also included. The performance of the proposed device, Barrier Sleeves, met the requirements of the biocompatibility testing conducted to support substantial equivalence with the primary predicate, Disposable Barrier Sleeves and Covers (K160232).

The performance testing (Bench) of the subject device, Barrier Sleeves, met the requirements of the non-clinical bench testing conducted to support substantial equivalence with the primary predicate, Disposable Barrier Sleeves and Covers (K160232). Below is a summary of the testing performed:
• 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

<table>
<thead>
<tr>
<th>Mechanical Property</th>
<th>Standard</th>
<th>Proposed Device Barrier Sleeves</th>
<th>Predicate Device Disposable Barrier Sleeves and Covers (K160232)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tensile Strength</td>
<td>ASTM D882</td>
<td>0.03mm – Comparable to Predicate</td>
<td>Acceptable for 0.03mm</td>
</tr>
<tr>
<td>Puncture Resistance</td>
<td>ASTM F1342/ F1342M</td>
<td>0.03mm – Comparable to Predicate</td>
<td>Acceptable for 0.03mm</td>
</tr>
<tr>
<td>Tear Resistance</td>
<td>ASTM D1004</td>
<td>0.03mm Comparable to Predicate</td>
<td>Acceptable for 0.03mm</td>
</tr>
</tbody>
</table>

The range of mechanical properties for the samples is reported for the proposed devices, Barrier Sleeves. Below is a summary of the testing performed:
• 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 range of mechanical properties for the samples of the proposed devices, Barrier Sleeves, is comparable to those reported for the predicate device, Disposable Barrier Sleeves and Covers (K160232). The results indicate the subject device passed performance testing under the conditions of the tests, and support the substantial equivalence of the subject device, Barrier Sleeves to its primary predicate, Disposable Barrier Sleeves and Covers (K160232).

Clinical Performance Data:
No data from human clinical studies have been included to support the substantial equivalence of the proposed devices, Barrier Sleeves as clinical studies are not required for this medical device.

Conclusions Regarding Substantial Equivalence:
The proposed device, Barrier Sleeves, consists of dental barrier sleeves and covers which are intended to serve as a disposable barrier for dental instruments and equipment. These barrier sleeves are non-sterile and are intended for single patient use only. The proposed device, Barrier Sleeves, have the same intended use and indications for use and incorporate the same fundamental technology and working principle, as the primary predicate device, Disposable Barrier Sleeves and Covers, cleared under premarket notification (K160232). Test data to verify the
performance of the proposed device, Barrier Sleeves, have been provided, including cytotoxicity, skin sensitization, oral mucosa irritation, synthetic blood penetration, synthetic blood penetration at seams and non-continuous components, viral penetration and viral penetration at seams and non-continuous components. The range of mechanical properties has been provided for puncture resistance, tear resistance, and tensile strength. The test results, combined with the design, intended use and mechanical property comparisons with the primary predicate device, support the substantial equivalence of the proposed Barrier Sleeves with its primary predicate device Disposable Barrier Sleeves and Covers (K160232).
Chemical composition / Biocompatibility / Shelf life
The chemical composition is identical. The biocompatibility of both device groups is the same as the devices are of the same material. The shelf life of the new devices is limited to 5 years on the recommendation of the material supplier.

Device performance
The device performance is the same for both groups of barriers and sleeves.