



ZimVie US Corp, LLC  
Ana Leitão  
Regulatory Affairs Manager Global  
4555 Riverside Dr.  
Palm Beach Gardens, Florida 33410

September 21, 2026

Re: K260940  
Trade/Device Name: BellaTek Bars  
Regulation Number: 21 CFR 872.3630  
Regulation Name: Endosseous Dental Implant Abutment  
Regulatory Class: Class II  
Product Code: NHA  
Dated: March 20, 2026  
Received: September 1, 2026

Dear Ana Leitão:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**ANDREW I. STEEN -S**

Andrew I. Steen  
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

510(k) Number (if known)  
K260940

Device Name  
BellaTek Bars

### Indications for Use (Describe)

The BellaTek Bars are indicated for attachment to dental abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The BellaTek Bars are intended for attachment to a minimum of two (2) abutments.

All digitally designed BellaTek Bars are intended to be sent to ZimVie for manufacture.

The BellaTek Bars are indicated for compatibility with the following abutment systems:

- DESS NobelActive®/ NobelReplace® Multi-Unit Abutment Systems
- DESS NobelActive®/ NobelReplace® MUA+ System
- DESS Nobel Replace Select™ Multi-Unit Abutment Systems
- DESS Nobel Brånemark Multi-Unit Abutment Systems
- DESS ZimVie External Hex Multi-Unit Abutment Systems
- DESS Straumann Bone Level Multi-Unit Abutment Systems
- DESS Straumann Bone Level MUA+ System
- DESS ZimVie Certain® Multi-Unit Abutment Systems
- DESS Straumann BLX® Multi-Unit Abutment Systems
- DESS Neodent Grand Morse (GM) Multi-Unit Abutment Systems
- DESS Neodent Grand Morse (GM) MUA+ System
- DESS ZimVie TSV® Multi-Unit Abutment Systems
- DESS Astra Tech EV® Multi-Unit Abutment Systems
- DESS Astra Tech Osseospeed Multi-Unit Abutment Systems
- DESS Biohorizons Internal Hex Multi-Unit Abutment Systems
- DESS Osstem® Multi-Unit Abutment Systems
- DESS MIS Seven® Multi-Unit Abutment Systems
- DESS Dentium Superline® & Implantium Multi-Unit Abutment Systems

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)

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**510(k) Summary - K260940**September 15<sup>th</sup>, 2026**Administrative Information**

Manufacturer Name: ZimVie US Corp LLC  
4555 Riverside Drive, Palm Beach Gardens, Florida 33410

Telephone: +351 917318533

Official Contact: Ana Leitão, Regulatory Affairs Manager Global  
Email: [ana.leitao@zimvie.com](mailto:ana.leitao@zimvie.com)

**Device Name and Classification**

Trade/Proprietary Name: BellaTek Bars  
Regulatory Class: Class II under the following:

| Regulation/Common Name             | Product Code | Regulation Number | Classification Panel  |
|------------------------------------|--------------|-------------------|-----------------------|
| Endosseous dental implant abutment | NHA          | 872.3630          | Dental Products Panel |

Reviewing Division: Division of Dental and ENT Devices

**Predicate Device Information**Primary Predicate Device:

- K241032 (SE 07/15/2024) – BellaTek Bars, ZimVie US Corp LLC (former Biomet 3i LLC)

Reference Devices:

- K170588 (SE 08/08/2017) – DESS Dental Smart Solutions
- K191986 (SE 11/10/2019) – DESS Dental Smart Solutions
- K212628 (SE 03/11/2022) – DESS Dental Smart Solutions
- K222288 (SE 10/27/2022) – DESS Dental Smart Solutions
- K231434 (SE 08/14/2023) – DESS Dental Smart Solutions
- K240208 (SE 04/24/2024) – DESS Dental Smart Solutions
- K252384 (SE 10/23/2025) – DESS Dental Smart Solutions

**Indications for Use Statement**

The BellaTek Bars are indicated for attachment to dental abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The BellaTek Bars are intended for attachment to a minimum of two (2) abutments.

All digitally designed BellaTek Bars are intended to be sent to ZimVie for manufacture.

The BellaTek Bars are indicated for compatibility with the following abutment systems:

- DESS NobelActive®/ NobelReplace® Multi-Unit Abutment Systems
- DESS NobelActive®/ NobelReplace® MUA+ System

- DESS Nobel Replace Select™ Multi-Unit Abutment Systems
- DESS Nobel Brånemark Multi-Unit Abutment Systems
- DESS ZimVie External Hex Multi-Unit Abutment Systems
- DESS Straumann Bone Level Multi-Unit Abutment Systems
- DESS Straumann Bone Level MUA+ System
- DESS ZimVie Certain® Multi-Unit Abutment Systems
- DESS Straumann BLX® Multi-Unit Abutment Systems
- DESS Neodent Grand Morse (GM) Multi-Unit Abutment Systems
- DESS Neodent Grand Morse (GM) MUA+ System
- DESS ZimVie TSV® Multi-Unit Abutment Systems
- DESS Astra Tech EV® Multi-Unit Abutment Systems
- DESS Astra Tech Osseospeed Multi-Unit Abutment Systems
- DESS Biohorizons Internal Hex Multi-Unit Abutment Systems
- DESS Osstem® Multi-Unit Abutment Systems
- DESS MIS Seven® Multi-Unit Abutment Systems
- DESS Dentium Superline® & Implantium Multi-Unit Abutment Systems

### Subject Device Description

The purpose of this submission is to seek clearance for additional bar-abutment compatibilities within an already cleared abutment-to-bar connection geometry.

The BellaTek Bars are intended to disperse the load of a prosthesis across dental implant-abutment assemblies. They also provide support for prosthetic devices such as artificial teeth, and to restore the patient's chewing function. The subject device is identical in every way to the primary predicate device BellaTek Bars cleared in K241032 (SE 07/15/2024) in terms of intended use, materials, compatibility with identical abutment-to-bar connection geometries and performance. Like the primary predicate device, the subject BellaTek Bars are either manufactured out of commercially pure titanium per ASTM F67 or of titanium alloy per ASTM F136. The BellaTek Bars are placed in a nylon bag and sealed in the same manner as the primary predicate device. Subject device BellaTek Bars is provided non-sterile in the same manner as the primary predicate device K241032 and is intended for single-patient, single use only.

Like the cleared primary predicate device, the BellaTek Bars are offered in two types. A Type I Bar is a Titanium Alloy bar designed for use with removable overdentures. A Type II Bar is a Pure Titanium or Titanium Alloy bar designed for fixed prosthesis. All BellaTek Bars (Dolder, Primary, Hader, Hybrid, Freeform, Canada, Wraparound and Copy Milled) are designed to match an individual patient. The bars are designed from a three-dimensional optical and/or digital scanner system that scans the casting of a patient's impression and then is machined using a CAD/CAM software system in accordance with customer specifications, within the limits of design defined in Tables 1 and 2.

*Table 1 Type I Bars: Removable*

| Description                | Minimum | Maximum |
|----------------------------|---------|---------|
| Platform Seating Diameter  | 3.4 mm  | 6.1 mm  |
| Total Cylinders            | 2       | 10      |
| Bar Span Between Cylinders | 0.0 mm  | 27.0 mm |

| Description                          | Minimum | Maximum |
|--------------------------------------|---------|---------|
| Bar Height                           | 2.5 mm  | 10.0 mm |
| Bar Width                            | 1.8 mm  | 10.0 mm |
| Distal Extension                     | 0.0 mm  | 10.7 mm |
| Cylinder Height                      | 0.0 mm  | 10.0 mm |
| Cylinder Diameter                    | 3.4 mm  | 10.0 mm |
| Maximum Angulation Between Cylinders | 0°      | 30°     |

*Table 2 Type II Bars: Fixed*

| Description                          | Minimum | Maximum |
|--------------------------------------|---------|---------|
| Platform Seating Diameter            | 3.4 mm  | 6.1 mm  |
| Total Cylinders                      | 2       | 10      |
| Bar Span Between Cylinders           | 0.0 mm  | 23.5 mm |
| Bar Height                           | 2.5 mm  | 22.0 mm |
| Bar Width                            | 4.0 mm  | 10.0 mm |
| Distal Extension                     | 0.0 mm  | 18.0 mm |
| Cylinder Height                      | 0.0 mm  | 19.5 mm |
| Cylinder Diameter                    | 3.4 mm  | 10.0 mm |
| Maximum Angulation Between Cylinders | 0°      | 30°     |

The BellaTek Bars are provided with an abutment-level connection interface. The BellaTek Bars include passive, non-indexing abutment-to-bar connection geometry with seating on the restorative platform of the multi-unit abutment as well as incorporate a screw seat that allows passage through and fixation with a Universal Multi-Unit prosthetic screw, supplier separately by Terrats Medical SL. Additionally, the occlusal surface of the BellaTek Bars may include bar-to-prosthesis connection geometry (e.g. female threads) to accept overdenture attachments.

#### Performance Data

Non-clinical data submitted or referenced to demonstrate substantial equivalence included:

- mechanical testing conducted according to ISO 14801 to support the performance of the subject device BellaTek Bars was leveraged from K241032.
- biocompatibility evaluation according to ISO 10993-1 demonstrating that the subject device does not introduce any increased risks or concerns regarding biocompatibility was leveraged from K241032.
- validated steam sterilization cycles as specified in the Instructions for Use were leveraged from K241032. Sterilization cycles were validated in accordance with ISO 17665-1, demonstrating a sterility assurance level (SAL) of  $10^{-6}$  of the device.
- compatibility analyses to demonstrate that the subject device is compatible with the abutment-to-bar connection of the reference devices was leveraged from K241032.

No clinical data will be included in this submission.

#### Equivalence to Marketed Devices

The primary predicate device (K241032) is in support of substantial equivalence of the subject device design specifications, material, and manufacturing.

The subject device BellaTek Bars has identical design matrix specifications as the primary predicate device cleared in K241032.

Subject device BellaTek Bars are provided non-sterile as the primary predicate devices. The subject device is packaged in a nylon bag pouch identical to the primary predicate device (K241032).

The reference devices (K170588, K191986, K212628, K222288, K231434, K240208, K252384) are identified as the compatible abutments.

**Conclusion**

The data included in this submission demonstrates substantial equivalence to the primary predicate device listed above.

Overall, the subject device has the following similarities to the primary predicate device:

- same intended use,
- same operating principles,
- incorporate the same basic designs,
- incorporate the same materials, and
- has same packaging and is sterilized using the same materials and processes.

The basis for the belief of ZimVie US Corp LLC that the subject device BellaTek Bars is substantially equivalent to the primary predicate device is summarized in the following Table of Substantial Equivalence.

Table 1 Table of Substantial Equivalence

| Comparison                            | Subject Device<br>BellaTek Bars                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Primary Predicate Device<br>BellaTek Bars<br>(K241032)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Comparison Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reason for predicate/reference        | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Indications for use, design matrix specifications, materials, and processing.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Indications for Use                   | <p>The BellaTek Bars are indicated for attachment to dental abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The BellaTek Bars are intended for attachment to a minimum of two (2) abutments.</p> <p>All digitally designed BellaTek Bars are intended to be sent to ZimVie for manufacture.</p> <p>The BellaTek Bars are indicated for compatibility with the following abutment systems:</p> <ul style="list-style-type: none"> <li>- DESS NobelActive®/ NobelReplace® Multi-Unit Abutment Systems</li> <li>- DESS NobelActive®/ NobelReplace® MUA+ System</li> <li>- DESS Nobel Replace Select™ Multi-Unit Abutment Systems</li> <li>- DESS Nobel Brånemark Multi-Unit Abutment Systems</li> <li>- DESS ZimVie External Hex Multi-Unit Abutment Systems</li> <li>- DESS Straumann Bone Level Multi-Unit Abutment Systems</li> <li>- DESS Straumann Bone Level MUA+ System</li> <li>- DESS ZimVie Certain® Multi-Unit Abutment Systems</li> <li>- DESS Straumann BLX® Multi-Unit Abutment Systems</li> <li>- DESS Neodent Grand Morse (GM) Multi-Unit Abutment Systems</li> <li>- DESS Neodent Grand Morse (GM) MUA+ System</li> <li>- DESS ZimVie TSV® Multi-Unit Abutment Systems</li> <li>- DESS Astra Tech EV® Multi-Unit Abutment Systems</li> <li>- DESS Astra Tech Osseospeed Multi-Unit Abutment Systems</li> <li>- DESS Biohorizons Internal Hex Multi-Unit Abutment Systems</li> <li>- DESS Osstem® Multi-Unit Abutment Systems</li> <li>- DESS MIS Seven® Multi-Unit Abutment Systems</li> <li>- DESS Dentium Superline® &amp; Implantium Multi-Unit Abutment Systems</li> </ul> | <p>The BellaTek Bars are indicated for attachment to dental abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The BellaTek Bars are intended for attachment to a minimum of two (2) abutments.</p> <p>All digitally designed BellaTek Bars are intended to be sent to ZimVie for manufacture.</p> <p>The BellaTek Bars are indicated for compatibility with the following abutment systems:</p> <ul style="list-style-type: none"> <li>• Universal Multi-Unit Abutments manufactured by Terrats Medical SL., 2.9-5.7mm, Angled, max 30° <ul style="list-style-type: none"> <li>- ZimVie Eztec Implant System</li> <li>- ZimVie TSX Implant System</li> <li>- ZimVie Tapered Screw-Vent System</li> </ul> </li> <li>• ZimVie Low Profile Abutments, 3.4-6.0mm, Angled, max 30° <ul style="list-style-type: none"> <li>- ZimVie Osseotite Implant System</li> <li>- ZimVie T3 and T3 PRO Implant System</li> </ul> </li> <li>• ZimVie Tapered Abutments, 3.5-5.7mm, Angled, max 30° <ul style="list-style-type: none"> <li>- ZimVie TSX Implant System</li> <li>- ZimVie Tapered Screw-Vent Implant System</li> </ul> </li> </ul> | <p>The subject device BellaTek Bars is substantially equivalent to the primary predicate device. Both are indicated for attachment to dental abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function.</p> <p>The subject BellaTek Bars are compatible with additional Terrats Medical SL multi-unit abutments that contain the same abutment-to-bar connection geometry as the abutments cleared for the primary predicate device.</p> |
| <b>Design</b>                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Bar shape                             | Type I (Dolder, Hader, Primary)<br>Type II (Combination Primary, Hybrid, Wraparound, Freeform, Canada, CopyMilled)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Type I (Dolder, Hader, Primary)<br>Type II (Combination Primary, Hybrid, Wraparound, Freeform, Canada, CopyMilled)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Identical for subject and primary predicate device.                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Platform seating diameter (min – max) | 3.4mm – 6.1mm (Type I)<br>3.4mm – 6.1mm (Type II)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 3.4mm – 6.1mm (Type I)<br>3.4mm – 6.1mm (Type II)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Identical for subject and primary predicate device.                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Number of total cylinders             | 2 – 10 (Type I and Type II)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 2 – 10 (Type I and Type II)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Identical for subject, primary and reference devices.                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Bar span between cylinders            | 0mm – 27mm (Type I)<br>0mm – 23.5mm (Type II)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 0mm – 27mm (Type I)<br>0mm – 23.5mm (Type II)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Identical for subject and reference devices.                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Bar Height                            | 2.5mm – 10mm (Type I)<br>2.5mm – 22mm (Type II)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 2.5mm – 10mm (Type I)<br>2.5mm – 22mm (Type II)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Identical for subject and primary predicate device.                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Bar Width                             | 1.8mm – 10mm (Type I)<br>4mm – 10mm (Type II)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 1.8mm – 10mm (Type I)<br>4mm – 10mm (Type II)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Identical for subject and primary predicate device                                                                                                                                                                                                                                                                                                                                                                                                                                            |

| Comparison                              | Subject Device<br>BellaTek Bars                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Primary Predicate Device<br>BellaTek Bars<br>(K241032)                                                                                                                                                                          | Comparison Summary                                                                                                                                                                                                                                           |
|-----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Distal Extension                        | 0mm – 10.7mm (Type I)<br>0mm – 18mm (Type II)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 0mm – 10.7mm (Type I)<br>0mm – 18mm (Type II)                                                                                                                                                                                   | Identical for subject and primary predicate device.                                                                                                                                                                                                          |
| Cylinder Height                         | 0mm – 10mm (Type I)<br>0mm – 19.5mm (Type II)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 0mm – 10mm (Type I)<br>0mm – 19.5mm (Type II)                                                                                                                                                                                   | Identical for subject and primary predicate device.                                                                                                                                                                                                          |
| Cylinder Diameter                       | 3.4mm – 10mm (Type I)<br>3.4mm – 10mm (Type II)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 3.4mm – 10mm (Type I)<br>3.4mm – 10mm (Type II)                                                                                                                                                                                 | Identical for subject and primary predicate device.                                                                                                                                                                                                          |
| Maximum Angulation Between<br>Cylinders | 0° - 30° (Type I)<br>0° - 30° (Type II)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 0° - 30° (Type I)<br>0° - 30° (Type II)                                                                                                                                                                                         | Identical for subject and primary predicate device.                                                                                                                                                                                                          |
| Mode of retention                       | Screw-retained                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Screw-retained                                                                                                                                                                                                                  | Identical for subject, primary and reference devices.                                                                                                                                                                                                        |
| Bar-Abutment mating<br>connection       | <ul style="list-style-type: none"> <li>- DESS NobelActive®/ NobelReplace® Multi-Unit Abutment Systems</li> <li>- DESS NobelActive®/ NobelReplace® MUA+ System</li> <li>- DESS Nobel Replace Select™ Multi-Unit Abutment Systems</li> <li>- DESS Nobel Brånemark Multi-Unit Abutment Systems</li> <li>- DESS ZimVie External Hex Multi-Unit Abutment Systems</li> <li>- DESS Straumann Bone Level Multi-Unit Abutment Systems</li> <li>- DESS Straumann Bone Level MUA+ System</li> <li>- DESS ZimVie Certain® Multi-Unit Abutment Systems</li> <li>- DESS Straumann BLX® Multi-Unit Abutment Systems</li> <li>- DESS Neodent Grand Morse (GM) Multi-Unit Abutment Systems</li> <li>- DESS Neodent Grand Morse (GM) MUA+ System</li> <li>- DESS ZimVie TSV® Multi-Unit Abutment Systems</li> <li>- DESS Astra Tech EV® Multi-Unit Abutment Systems</li> <li>- DESS Astra Tech Osseospeed Multi-Unit Abutment Systems</li> <li>- DESS Biohorizons Internal Hex Multi-Unit Abutment Systems</li> <li>- DESS Osstem® Multi-Unit Abutment Systems</li> <li>- DESS MIS Seven® Multi-Unit Abutment Systems</li> <li>- DESS Dentium Superline® &amp; Implantium Multi-Unit Abutment Systems</li> </ul> | <p>Universal Multi-Unit Abutments manufactured by Terrats Medical SL.,<br/>2.9-5.7mm, Angled, max 30°<br/>ZimVie Low Profile Abutments, 3.4-6.0mm, Angled, max 30°<br/>ZimVie Tapered Abutments, 3.5-5.7mm, Angled, max 30°</p> | Identical for subject and primary predicate device, with additional compatibilities with Terrats Medical SL multi-unit abutments that contain the same abutment-to-bar connection geometry as the abutments cleared in the primary predicate device K241032. |
| <b>Materials and Manufacturing</b>      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                              |
| Bar material                            | Ti-6Al-4V ELI (ASTM F136) or Grade 4 CP Titanium (ASTM F67)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Ti-6Al-4V ELI (ASTM F136) or Grade 4 CP Titanium (ASTM F67)                                                                                                                                                                     | Identical for subject and primary predicate device.                                                                                                                                                                                                          |
| Packaging                               | Nylon pouch                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Nylon pouch                                                                                                                                                                                                                     | Identical for subject and primary predicate device.                                                                                                                                                                                                          |
| Sterilization                           | Non-sterile                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Non-sterile                                                                                                                                                                                                                     | Identical for subject and primary predicate device.                                                                                                                                                                                                          |