June 17, 2020

ReOss GmbH
% Viky Verna
Co-founder and Vice President (US office)
confinis
15807 Glacier Court
North Potomac, Maryland 20878

Re: K192747
Trade/Device Name: Yxoss CBR®
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: May 12, 2020
Received: May 20, 2020

Dear Viky Verna:

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,

for

Srinivas Nandkumar, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K192747

Device Name
Yxoss CBR®

Indications for Use *(Describe)*
Yxoss CBR® is used for reconstruction of alveolar bone deficits prior to placing a dental implant, shaping alveolar bone and as a support to the augmented bone volume in the regeneration of bone defects that may include:
• extraction sites
• horizontal and/or vertical augmentation of the alveolar ridge
• reconstruction of bone defects in the maxillofacial area

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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## 5. 510(k) Summary

In accordance with 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

**Applicant:**

| | |
|---|---|
| Submitter name: | ReOss GmbH |
| Responsible person: | Michael Peetz |
| Phone: | +49 711 489 660 60 |
| E-mail: | mp@reoss.eu |

**Official Correspondent**:

| | |
|---|---|
| Contact person: | Viky Verna, MS BME, MS Pharm, RAC |
| Phone: | 786-525-9811 |
| E-Mail: | Viky.verna@confinis.com |
| Date prepared: | 16-June-2020 |

**Device Name**:

| | |
|---|---|
| Proprietary name: | Yxoss CBR® |
| 510(k) number: | K192747 |
| Common name: | Bone Plate |
| Classification name: | Bone Plate, 21 CFR 872.4760 |
| Product code: | JEY |

**Predicate Device:**

Substantial Equivalence is claimed with the device, K172354 OssBuilder System, manufactured by Osstem Implants Co., Ltd. on the basis of equivalent intended use, technological characteristics and principle of operation.

This predicate has not been subject to a design-related recall.

**Device Description:**

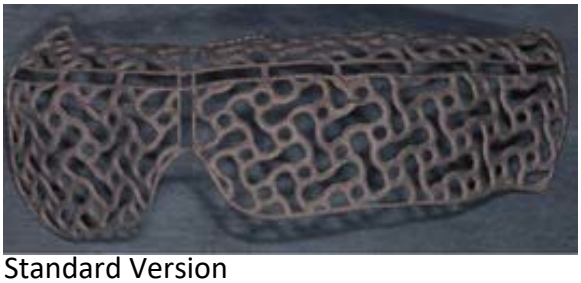
Yxoss CBR is a titanium scaffold, which will be surgically inserted over bone defects as a volume support for contouring newly formed bone over a bone defect. The titanium scaffold is held in place to the existing bone with standard titanium screw(s). The following screws are compatible with the Yxoss CBR device system (informational purposes only, not devices subject to this sub-mission, K192747): Synthes 1.3mm self-drilling screws, K983485, and Salvin Dental 1.5mm Tent-ing Screws, K161857. Yxoss CBR thus stabilize the bone graft in the defect area and specifies the shape of the bone to be augmented.

The Yxoss CBR may be used in a one-stage approach with simultaneous placement of a dental implant. The Standard Yxoss scaffold (without integrated implant positioning) is used to cover over the simultaneously placed bone level dental implant with cover screw. The Standard Yxoss scaffold is explanted after healing occurs, leaving in place the dental implant.

In a two-stage approach, the dental implant will be placed after revascularization of the augmented bone. In a two-stage approach, there are two options available:

- Standard Yxoss scaffold (without integrated implant positioning)
- Backward Yxoss scaffold (with integrated implant positioning)

For the two-stage approach, the Standard Yxoss scaffold will be removed before placing the dental implant. For the Backward Yxoss scaffold using the two-stage approach, the pre-holes are used as guide for drilling the seat before inserting the dental implant chosen by the surgeon. Then, the Backward Yxoss scaffold will be explanted.


Standard Version


Backward Version

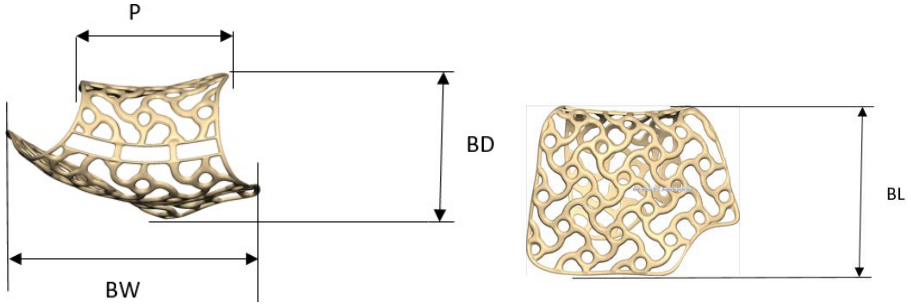
The outer dimensions are valid for Yxoss CBR® Standard and Backward version. The backward version has a ring-formed hole to offer the possibility to the surgeon to place a dental implant at his discretion in parallel with the placement of the Yxoss CBR®.

**Design envelope of Yxoss CBR®**

The Yxoss implant is designed to be used from a one tooth use up to 8 teeth, corresponding to 50% of the jaw.

The design envelope is provided in the following table based on the 4 dimensions shown in the sample picture below.

| **Envelope dimension [mm]** | |
|---|---|
| Proximal - P | 5 – 36 mm |
| Buccal width - BW | 9 – 50 mm |
| Buccal length - BL | 7 - 11 mm |
| Buccal distance - BD | 5.5 – 16mm |



The system can only be used by specially trained dentists, specialized dental practitioners and medical specialists with appropriate qualifications and experience.

The device is manufactured by SLS (Selective Laser Sintering) additive manufacturing.

**Indications for Use:**

Yxoss CBR® is used for reconstruction of alveolar bone deficits prior to placing a dental implant, shaping alveolar bone and as a support to the augmented bone volume in the regeneration of bone defects that may include:

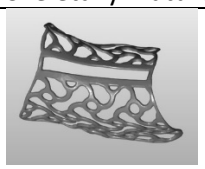
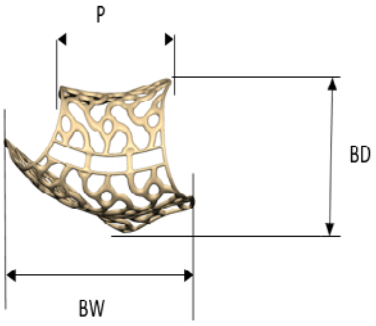
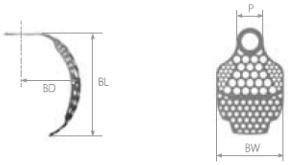
- extraction sites
- horizontal and/or vertical augmentation of the alveolar ridge
- reconstruction of bone defects in the maxillofacial area

**Comparison of Technological Characteristics:**

Table 05-1 provides a comparison of the predominant technical characteristics of the subject device and the legally marketed predicate device.

**Table 05-1: Comparison of Technological Characteristics**

| Description | Subject Device | Primary Predicate Device | Rationale for difference |
|---|---|---|---|
| Device Name | Yxoss CBR | OssBuilder System | n/a |
| 510(k) Number | K192747 | K172354 | n/a |
| Manufacturer | ReOss GmbH | Osstem Implants Co., Ltd. | n/a |
| Prescription device | Yes | Yes | Same |
| FDA Product Code | JEY | JEY, NHA | The additional product code NHA is for components of the abutment. These are not provided by ReOss GmbH. |
| Indications for Use | Yxoss CBR® is used for reconstruction of alveolar bone deficits prior to placing a dental implant, shaping alveolar bone and as a support to the augmented bone volume in the regeneration of bone defects that may include:<br>• extraction sites<br>• horizontal and/or vertical augmentation of the alveolar ridge<br>• reconstruction of bone defects in the maxillofacial area | OssBuilder System is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alvolar bony defect sites. | Both the Yxoss CBR® and the predicate device are used in stabilization and support of bone graft in dento-alvolar bony defect sites.<br>The Yxoss CBR® indications for use statement provides more detailed information to cover the intended use, however, even if phrased differently, both devices are addressing the same medical issue. |

| Description | Subject Device | Primary Predicate Device | Rationale for difference |
|---|---|---|---|
| Population | Skeletally mature patients | Skeletally mature patients | Same |
| Design |  |  | The subject and predicate device have both scaffold like structure. The Yxoss CBR® are patient-specific scaffolds. |
| Size Range (*) |  |  | |
| | Proximal – P: 5 – 36 mm | Proximal – P: 4 – 12 mm | The OssBuilder minimum dimension corresponds to the outer diameter of the fixation hole, while the maximum dimension is designed to cover 1 tooth defect. Coverage of more than 1 tooth defect is achieved by combining more than 1 scaffold, i.e 3 OssBuilder will make up max length of the Yxoss CBR ®.<br>Yxoss CBR® minimum dimension is within the range of the predicate device. The maximum dimension for the proximal dimension considers coverage up to 8 teeth or 50% of the full jaw. This is possible using the patient specific design. |

| Description | Subject Device | Primary Predicate Device | Rationale for difference |
|---|---|---|---|
| | Buccal Width – BW: 9 – 50 mm | Buccal Width – BW: 8 – 20 mm | The Buccal width minimum dimension of the Yxoss CBR® is in the range of the predicate device, while the maximum differs as the device can be designed to cover up to 8 teeth or 50% of the full jaw. This is possible using the patient specific design. |
| | Buccal Length – BL: 7 – 11 mm | Buccal Length – BL: 7 – 9 mm | The buccal length depends on the defect size and the height of the alveolar ridge. The design approach of Yxoss orients at the remaining bone substance and requires 2mm of additional height to contact the remaining bone. The dimensions for the Buccal length of the subject are slightly higher than the ones for the predicate device. The design of the OssBuilder provides mainly coverage of 1 side wall of the jaw while Yxoss CBR® can be designed for individual patients to cover both sides of the jaw. |
| | Buccal distance – BD: 5.5 – 16 mm | Buccal distance – BD: 5.5 mm | Yxoss CBR® is designed to cover both sides of the jaw and thus dimensions are bigger. Furthermore, the BD for the OssBuilder is taken starting from the center of the hole and does not consider the complete implant. |
| Material | Pure Titanium Grade 2 (ASTM F67) | Pure Titanium Grade 2 (ASTM F67) | Same |
| Sterilization | N/A – non-sterile | Gamma Sterilization | The subject device is delivered in a double peel pouch and intended to be sterilized prior use. |

| Description | Subject Device | Primary Predicate Device | Rationale for difference |
|---|---|---|---|
| Shelf Life | N/A | 8 years | Shelf-life depending from sterilization materials used. |

(*) NOTE: As described in the table above a one-to-one comparison between the dimensions of the two implants is not fully possible since the OssBuilder is designed with a discreet range of sizes, and the Yxoss CBR® is designed for the individual patient. The two designs achieve the same intended purpose. Discreet dimensions are not considered for a one-to-one comparison; the "envelope" is considered in view of allowing patient specific implants. The "envelope" of range of dimensions for the Yxoss CBR® has been designed considering scientific literature and existing clinical cases and has been validated for use covering 50% of a full jaw.

The Yxoss CBR® devices for all versions are held in place at the bone defect sites by specific compatible fixation screws, while the OssBuilder is designed for fixation by mating directly with specific compatible dental implant systems. The two designs achieve the same purpose for maintaining device fixation at the bone defect site.

**Summary of Non-Clinical Testing:**

Sterilization validation: The validated sterilization method to achieve a SAL of $10^{-6}$ using the half cycle method per AAMI ST79 and EN 556-1 is steam sterilization (Dynamic Air Re moval) at 132°C for 4 minutes.

Packaging validation: The sterile barrier system complies with ISO 11607-1.

Biocompatibility: Biological evaluation has been performed in accordance with ISO 10993-1; Chemical Analysis according to ISO 10993-12, ISO 10993-15, and ISO 10993-18; and Cytotoxicity testing according to ISO 10993-5 and ISO 10993-12 were performed on worst case components of the Yxoss CBR®.

Mechanical tests: The trabecular structure has been characterized by chemical characterization (chemical analysis, powder size distribution, reuse of powder, build plate orientation), mechanical testing (tensile tests of samples from different manufacturing orientations and positions), geometrical measurements (evaluation of process capability), and surface blast treatment and cleaning assessment (chemical analyses, photomicrographs).

**Summary of Clinical Performance Data:**

Clinical Evaluation: A scientifically-based clinical justification with supporting literature and an expert opinion of an operating surgeon using the Yxoss CBR® Implant has been provided to support exceeding the cleared size ranges of the primary predicate to demonstrate clinical use for all the proposed indications of the subject devices. The clinical evaluation included five years of market data, involving 300 patients covering the size range from 1 to 8 teeth (50% of the jaw) to show successful restoration of bone volume for dental implant placement. Also, a clinical literature review was provided to support the size of the device as compared to healing for similar sized bone defects to demonstrate soft tissue response and management with the proposed surgical protocol. This information supported preventing early graft exposure and tension-free wound closure to not compromise the final treatment outcome.

**Conclusion:**

Based on equivalence of indications for use, technological characteristics and operational principle the applicant concludes that substantial equivalence between the new and the predicate device has been demonstrated and that the subject device, Yxoss CBR, is substantially equivalent to the legally marketed predicate device, OssBuilder System (K172354).