OsseoFuse, Inc.
C/O Priscilla Chung
LK Consulting Group USA, Inc.
2651 East Chapman Avenue, Suite 110
Fullerton, CA 92831

Re: K133050
Trade/Device Name: One Plus Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endossesous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: August 20, 2014
Received: August 21, 2014

Dear Ms. Chung:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K133050

Device Name
One Plus Implant System

Indications for Use (Describe)

The One Plus Implant System is intended to use in the treatment of missing teeth to support prosthetic device, such as artificial teeth, in order to restore mastication in partially edentulous patients. 3.0mm diameter implants are intended to be used in central or lateral mandibular incisors. The One Plus Implant System is intended for single use only. It is for delayed loading.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)
510(k) Summary
(K133050)

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 09/17/2014

1. Applicant / Submitter

OsseoFuse, Inc.

5023 North Parkway Calabasas,
Calabasas, CA 91302
Tel. 888.446.9995
Fax. 310.356.3183

2. Submission Correspondent

LK Consulting Group USA, Inc.
2651 E Chapman Ave. Ste 110, Fullerton CA 92831
Priscilla Chung
Phone: 714.202.5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

- Trade Name: One Plus Implant System
- Common Name: Dental Implant
- Classification Name: Endosseous Dental Implant System
- Product Code: DZE
- Classification regulation: 21CFR872.3640

4. Predicate Device:

- MS System by OSSTEM IMPLANT CO., LTD (K083067)
- S-MINI IMPLANT SYSTEM by NEOBIOTECH CO., LTD (K112540)
- OSSEOFUSE DENTAL IMPLANT SYSTEM by Dynamic Innovations Inc. (K110577)
- Spectra System (ScrewDirect Implant) by Implant Direct LLC (K061319)
- Replace One Piece Implant by NOBEL BIOCARE UAS INC. (K023952)
- Lifecore PrimaSolo One-Piece Implant System by Lifecore Biomedical, Inc.(K050506)
5. **Description:**

The One Plus Implant System is a dental implant system made of Titanium 6AL 4V ELI Gr.23 alloy intended to be surgically placed in the bone of the upper or lower jaw arches. The system is similar to other commercially available products based on the intended use, the technology used, the material composition employed and performance characteristics. The surface of this system has been treated with R.B.M and the abutment part has TiN coating on it.

The One Plus Implant System is available in the following sizes.

Sizes: 3.00mm (Dia.) x 11.5/13/14.5  
3.75mm (Dia.) x 11.5/13/14.5  
4.50mm (Dia.) x 11.5/13/14.5  
5.25mm (Dia.) x 11.5/13/14.5

6. **Indication for use:**

The One Plus Implant System is intended to use in the treatment of missing teeth to support prosthetic device, such as artificial teeth, in order to restore mastication in partially edentulous patients. 3.0mm diameter implants are intended to be used in central or lateral mandibular incisors. The One Plus Implant System is intended for single use only. It is for delayed loading.

7. **Basis for Substantial Equivalence**

The subject device is substantially equivalent to the noted predicate devices based on tabulated device specifications and properties presented. Based on the comparison analysis, the identical intended use, comparable technological characteristics, and similar general design features, the subject device is substantially equivalent to the predicate devices. There are no significant differences between the One Plus Implant System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to the predicate devices in design, function, material and intended use.

The comparison chart can be found on the following pages.
## Comparison Chart

<table>
<thead>
<tr>
<th>510(K) Number</th>
<th>Subject Device</th>
<th>Predicate Device 1</th>
<th>Predicate Device 2</th>
<th>Predicate Device 3</th>
<th>Predicate Device 4</th>
</tr>
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<tbody>
<tr>
<td>K133050</td>
<td>One Plus Implant System</td>
<td>K083067</td>
<td>K112540</td>
<td>OSSEOFUSE DENTAL IMPLANT SYSTEM</td>
<td>Spectra System (ScrewDirect Implants)</td>
</tr>
<tr>
<td>K083067</td>
<td>K083067</td>
<td>S-MINI IMPLANT SYSTEM</td>
<td>K110577</td>
<td>Dynamic Innovations Inc.</td>
<td>Implant Direct LLC</td>
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<td>K112540</td>
<td>S-MINI IMPLANT SYSTEM</td>
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<td>K110577</td>
<td>-</td>
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<td>K110577</td>
<td>OSSEOFUSE DENTAL IMPLANT SYSTEM</td>
<td>-</td>
<td>-</td>
<td>KJ Meditech Co., Ltd.</td>
<td>-</td>
</tr>
<tr>
<td>K061319</td>
<td>Spectra System (ScrewDirect Implants)</td>
<td>-</td>
<td>-</td>
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</tbody>
</table>

### Device Name

- **One Plus Implant System**
- **MS System**
- **S-MINI IMPLANT SYSTEM**
- **OSSEOFUSE DENTAL IMPLANT SYSTEM**
- **Spectra System (ScrewDirect Implants)**
- **Cement Type**

### Applicant

- **OsseoFuse Co., Ltd.**
- **OSTEM Implant Co., Ltd.**
- **NEOBIOTECH CO., LTD.**
- **Dynamic Innovations Inc.**
- **Implant Direct LLC**

### Contract Manufacturer

- **KJ Meditech Co., Ltd.**

### Indications for Use

**The One Plus Implant System** is intended to use in the treatment of missing teeth to support prosthetic device, such as artificial teeth, in order to restore mastication in partially edentulous patients. 3.0mm diameter implants are intended to be used in central or lateral mandibular incisors. The One Plus Implant System is intended for single use only. It is for delayed loading.

**The MS System** is intended to be placed in the bone of the upper or lower jaw arches to provide support to the prosthetic devices to restore the patient's chewing function, including the denture stabilization. **The MS System (Denture)** is intended for single use only.

**The Spectra Dental Implant System** consists of one-piece or two-piece implants for single-stage or two-stage surgical procedures that are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. They may be placed in immediate function if initial implant stability can be established.

### The Cement Type

The Cement type is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to serve as temporary support prosthetic devices during the healing phase of permanent endosseous dental implant, such as artificial teeth, in order to restore chewing function in partially edentulous patients.

### The OsseoFuse Dental Implant System

The OsseoFuse Dental Implant System is intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures and not dedicated for immediate loading. This system is intended for delayed loading.

### The ScrewDirect 3.0mm implant

1. An artificial root structure for single tooth replacement of mandibular central and lateral incisors
immediate loading.

and maxillary lateral incisors.

2. Multiple tooth replacements or denture stabilization.

<table>
<thead>
<tr>
<th>Design</th>
<th>One Piece Implant</th>
<th>One Piece Implant</th>
<th>One Piece Implant</th>
<th>Two Piece Implant</th>
<th>One Piece Implant</th>
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<tbody>
<tr>
<td>Appearance</td>
<td></td>
<td></td>
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<tr>
<td>Material</td>
<td>Ti 6Al 4V ELI, Gr.23</td>
<td>Titanium Alloy</td>
<td>Titanium Gr. 4</td>
<td>Ti 6Al 4V ELI, Gr.23</td>
<td>Titanium Alloy</td>
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<td>Surface Treatment</td>
<td>•RBM Treatment on the fixture body •TiN coating on the abutment</td>
<td>RBM Treatment on the fixture body</td>
<td>RBM Treatment on the fixture body</td>
<td>•RBM Treatment on the fixture body •TiN coating on the abutment</td>
<td>Roughened – HA blasted</td>
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<td>Gamma</td>
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<tr>
<td>Implant Sterile</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
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<td>2.0mm, 2.5mm, 3.0mm, 3.5mm</td>
<td>3.75mm, 4.1mm, 4.5mm, 5.25mm</td>
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<td>Implant Lengths</td>
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<td>7.0 – 15.00 mm</td>
<td>8.5mm – 16.0 mm</td>
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<tr>
<td><strong>Device Name</strong></td>
<td>Lifecore PrimaSolo™ One-Piece Implant System</td>
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<td><strong>Applicant</strong></td>
<td>NOBEL BIOCARE UAS INC.</td>
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<td><strong>Applicant</strong></td>
<td>LIFECORE BIOMEDICAL, INC.</td>
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<tr>
<td><strong>Indications for Use</strong></td>
<td>Lifecore Biomedical Dental Implant System implants are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. Specific Intended Uses: The PrimaSolo One-Piece (3.5-5.0mm) Implant is a threaded one-piece implant with integrated abutment designed for single-stage surgical procedure and cemented restorations. The PrimaSolo One-Piece Implant is intended for immediate placement and can be restored with a temporary prosthesis in single tooth and multiple tooth applications with good quality bone. The PrimaSolo One-Piece (3.0mm) Implant is a threaded one-piece implant with an integrated abutment designed for single-stage surgical procedure and is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. Mandible central and lateral incisors must be splinted if using two or more 3.0mm implants adjacent to one other.</td>
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<td><strong>Design</strong></td>
<td>One Piece Implant</td>
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<td>Sterilization Method</td>
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</tr>
<tr>
<td>Implant Diameters</td>
<td>3.5mm, 4.3mm, 5.0mm, 3.0mm, 3.5mm, 4.1mm, 5.0mm</td>
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</table>
8. Non-Clinical Testing

▪ Sterilization validating testing has been performed in accordance with ISO 11137-1, ISO 11137-2 and ISO 11137-3.
▪ Accelerated shelf life testing has been performed in accordance with ASTM1980-07, ISO 11607-1, ISO 11737-1, ISO 11737-2
▪ Chemical and SEM image analyses have been performed to verify that there is no residual after RBM treatment on the fixture.

There might be differences in sterilization parameters, shelf life and manufacturing processes between the subject device and the predicate devices, however, the test results supported that the subject device is substantially equivalent to the predicate devices.

9. Conclusion

The subject device and the predicate devices have the same intended use and have similar technological characteristics.

Overall, the One Plus Implant System has the following similarities to the predicate devices:

▪ has the same intended use,
▪ uses the same operating principle,
▪ incorporates the same basic design,
▪ incorporates the same material and the surface treatment.

Based on the similarities, we conclude that the One Plus Implant System is substantially equivalent to the predicate devices.