DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 27, 2017

Insight Dental System
c/o David Furr
Regulatory Correspondent
FDC Services
8708 Capehart Cove
Austin, Texas 78733

Re: K170211
Trade/Device Name: Insight Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: March 31, 2017
Received: April 3, 2017

Dear David Furr:

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 http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170211

Device Name
Insight Dental Implant System

Indications for Use *(Describe)*
The Insight Dental Implant System is intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. The Insight Dental Implant System is intended 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary Pursuant to 21 CFR 807.92

Date: April 17, 2017
K170211

1.	Submitted By:	Insight Dental System 4766 Research Drive San Antonio, Texas 78240 888-255-7935
2.	Contact:	David C. Furr FDC Services, LLC 8708 Capehart Cove Austin, Texas 78733 512-906-9654
3.	Product:	Insight Dental Implant System Regulation: 21CFR§872.3640 Class II Product Codes: DZE Implant, Endosseous, Root Form NHA Abutment, Implant, Dental, Endosseous
4.	Trade Name: Common Name: Regulation Name:	Insight Dental Implant System Dental Implant & Abutment System Endosseous Dental Implant
5.	Primary Predicate:	BioHorizons Tapered Internal Implants K143022
6.	Reference Predicates:	BioHorizons Laser-Lok 3.0 Implant System K093321 BioHorizons Tapered Internal Implant System K071638

Description:

The Insight Dental Implant System is an integrated system of endosseous dental implants which are designed to support prosthetic devices for partially or fully endetulous patients. The Insight Dental Implant System consists of one-stage and two-stage root form dental implants and abutments, which provide the dentist with screw retained restoration options. The devices covered by this submission are implants, abutments, and healing caps.

Implants are manufactured from titanium and feature a blasted finish on the threaded screw surface. The implants are provided in bone level and tissue level. The diameters of the implant fixtures are 3.5mm, 3.8mm, 4.6mm and 5.4mm; the lengths are 8.0mm, 10.0mm, and 12.0mm and is defined as the threaded implanted portion of the implant.

Abutments are available in both standard and angled configurations. Abutments are manufactured from titanium. Standard abutments are straight, 4.6mm in diameter and sized for every implant diameter including 3.5mm, 3.8mm, 4.6mm and 5.4mm. Angled abutments are 17º, 4.9mm in diameter and sized for every implant diameter including 3.5mm, 3.8mm, 4.6mm and 5.4mm.

Healing caps are manufactured from titanium. The diameter of each healing cap matches an implant at 3.5mm, 3.8mm, 4.6mm and 5.4mm. Healing caps are straight.

The dental implants provided consist of a straight wall or tapered body type with a basic screw-type design in various platform options and feature an internal connection and anti-rotation feature. Insight Dental Implant System is available with either prevail platform switching feature or standard collar.

The Insight Dental System is packaged in a two section sterile tray with all of the implants and instruments needed for a single procedure included. All components of the system are intended for single use only.

Indications for Use:

The Insight Dental Implant System is intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. The Insight Dental Implant System is intended for delayed loading.

Substantial Equivalence/Technological Characteristics:

The subject device is substantially equivalent to the BioHorizons Tapered Internal Implant System which is based on BioHorizons premarket notification (K143022). BioHorizon premarket notifications K071638 and K093321 were also used as reference predicate devices.

The subject device and the predicate devices have a similar intended use, design, technological characteristics, principals of operation, and are made of the same materials. The subject device and predicate devices encompass a similar range of physical dimensions, including diameter and length of the implants and diameter, height, and angle of the abutments. The subject and predicate devices are packaged in similar materials and sterilized using irradiation. Any differences do not raise new issues of substantial equivalence.

510(k) Premarket Notification
Insight Dental Implant System

Element of Comparison	**510(k) Device:** Insight Dental System	**Primary Predicate Device:** BioHorizons Tapered Internal Implant System K143022	**Reference Device:** BioHorizons Laser-Lok 3.0 Implant System K093321	**Reference Device:** BioHorizons Tapered Internal Implant System K071638	**Explanation of Differences**
Regulation and Product Classification Code	21 CFR 872.3640 DZE NHA	21 CFR 872.3640 DZE 21 CFR 872.3630 NHA	21 CFR 872.3640 DZE 21 CFR 872.3630 NHA	21 CFR 872.3640 DZE 21 CFR 872.3630 NHA	None
Indications for Use	The Insight Dental Implant System is intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. The Insight Dental Implant System is intended for delayed loading.	The BioHorizons Tapered Internal Implant System is intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. The BioHorizons Tapered Implant System may be restored immediately (1) with a temporary prosthesis that is not in functional occlusion or (2) when splinted together for multiple tooth replacement or when stabilized with an overdenture supported by multiple implants.	The BioHorizons Tapered Internal Implant System is intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. The BioHorizons Tapered Implant System may be restored immediately (1) with a temporary prosthesis that is not in functional occlusion or (2) when splinted together for multiple tooth replacement or when stabilized with an overdenture supported by multiple implants.	The BioHorizons Tapered Internal Implant System is intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. The BioHorizons Tapered Implant System may be restored immediately (1) with a temporary prosthesis that is not in functional occlusion or (2) when splinted together for multiple tooth replacement or when stabilized with an overdenture supported by multiple implants.	The IDS device is intended for delayed loading but differences are not significant when used.
Principal Material Formulation of Implants	Ti-6AL-4V-ELI	Ti-6AL-4V-ELI	Ti-6AL-4V-ELI	Ti-6AL-4V-ELI	Identical
Implant Shape, Diameters and Length	Tapered Shape 3.5, 3.8, 4.6, 5.4mm diameters 8.0, 10.0, 12.0 mm implanted Lengths	Tapered Shape 3.0, 3.5, 4.5mm diameters 9.0, 10.5, 12.0, 15, 18mm Lengths	Parallel wall with 2.5mm apical taper 3.0mm diameter 10.5, 12.0, 15mm Lengths	Tapered Shape 3.5, 4.5. 5.7mm diameters 7.5, 9.0, 10.5, 12.0, 15mm Lengths	BioHorizons has a slightly smaller and larger size, but subject device is bracketed within the limits of the predicate. No significant differences.

510(k) Premarket Notification
Insight Dental Implant System

Element of Comparison	**510(k) Device:** Insight Dental System	**Primary Predicate Device:** BioHorizons Tapered Internal Implant System K143022	**Reference Device:** BioHorizons Laser-Lok 3.0 Implant System K093321	**Reference Device:** BioHorizons Tapered Internal Implant System K071638	**Explanation of Differences**
Abutments	Abutment diameters 3.5, 3.8, 4.6, 5.4mm	N/A (references to K093321)	Abutment diameters 3.5, 3.8, 4.2, 4.5, 4.7, 5.5, 5.8, 5.9, 6.6, 6.8mm	N/A	BioHorizons has slightly different and larger sizes, but subject device is bracketed within the limits of the predicate. No significant differences.
Principal Material Formulation of Abutments	Ti-6AL-4V-ELI	Ti-6AL-4V-ELI	Ti-6AL-4V-ELI	Ti-6AL-4V-ELI	Identical
Healing caps	Healing cap diameters 3.5, 3.8, 4.6 and 5.4mm	N/A (references to K093321)	Healing cap diameters 3, 3.5, 4.5, 5.7mm	N/A	BioHorizons has slightly different and larger sizes, but subject device is bracketed within the limits of the predicate. No significant differences.
Principal Material Formulation of Healing caps	Ti-6AL-4V-ELI	Ti-6AL-4V-ELI	Ti-6AL-4V-ELI	Ti-6AL-4V-ELI	Identical
Principal Material Formulation of Class I Accessories	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel	No significant differences
Packaging	Tyvek Lidded Blister Tray	Tyvek Lidded Blister Tray	Tyvek Lidded Blister Tray	Tyvek Lidded Blister Tray	No significant differences
Sterility	Single Use Gamma Sterilized	Single Use Gamma Sterilized	Single Use Gamma Sterilized	Single Use Gamma Sterilized	Identical

Summary of Testing

The technological characteristics of the Insight Dental Implant System have been verified to be essentially the same as the predicate devices based on assessments of material composition, dimensional features, mechanical properties and biocompatibility of the implant and instrument materials. Comparative Dynamic Fatigue testing was performed to show equivalence to the predicate device. This testing was performed according to ISO-14801-2007, Dynamic fatigue test for endosseous dental implants for both bone level and tissue level implants.

Surface treatment was evaluated using SEM images, X-ray spectroscopy and auger electron spectroscopy of titanium surfaces.

Cytotoxicity testing according to ISO 10993-5 was also done on the implants materials to demonstrate that the manufacturing process did not change the biocompatibility profile. No additional biocompatibility testing was deemed necessary since the devices are constructed from medical quality titanium.

Shelf life testing has been conducted by accelerated aging according to ASTMF1980-07 and a 1 year shelf life has been established. Shelf life testing included visual inspection, seal strength and bubble testing.

Insight Dental Implant kits are sterilized by gamma irradiation. Validation was done to IS01137-1. The Sterility Assurance Level (SAL) for the product sterilization process is 10^{-6}. Dosage is a minimum of 25 kGy exposure. Validation was done using the VDmax 25 method (ISO 11137-2). Devices are not labeled as non-pyrogenic.

No clinical test data was used to support the decision of substantial equivalence.

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notifications the Insight Dental Implant System is substantially equivalent to predicate devices as described herein.