Huvexel Co., Ltd
% Mr. Milan George
Senior Director
Dio Medical Corporation
8770 W Bryn Mawr Avenue
Ste. 1250
Chicago, Illinois 60631

October 31, 2017

Re: K173080
Trade/Device Name: IVA Cage Ti (ACIF, PLIF, TLIF, DLIF, and ALIF)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: September 28, 2016
Received: September 29, 2017

Dear Mr. George:

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 (DICE) 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 (DICE) 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173080

Device Name
IVA CAGE Ti (ACIF, PLIF, TLIF, DLIF and ALIF)

Indications for Use *(Describe)*

The IVA Cage (ACIF, Ti ACIF) are indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage

The IVA Cage (PLIF, TLIF, DLIF, ALIF,Ti PLIF, Ti TLIF, Ti DLIF and Ti ALIF) are indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at one level of two continuous levels for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

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.

510(k) SUMMARY

HUVEXEL Co., Ltd's
IVA CAGE Ti (ACIF, PLIF, TLIF, DLIF and ALIF)

Sponsor:	Manufacturer	HUVEXEL Co., Ltd. 101-105 Megacenter, SK Technopark 124 Sagimakgol-ro, Jungwon-gu Seongnam-si Gyeonggi-do, South Korea
	Official Contact Phone: Fax:	Milan George 267-737-9496 x102 847-795-1079
		September 28, 2017
Device Name:	**IVA CAGE Ti (ACIF, PLIF, TLIF, DLIF and ALIF)**	
Common Name:	**Intervertebral Body Fusion Device**	
Classification Name:	**Intervertebral Body Fusion Device, Cervical** **Intervertebral Body Fusion Device, Lumbar**	
Classification Number:	**21 CFR 888.3080**	
Product Code/Classification:	**ODP, MAX class II**	
Description:	The IVA Cage Ti (ACIF, PLIF, TLIF, DLIF and ALIF) is intended for intervertebral body fusion in skeletally mature patients. The intended operation of these devices are concentrated around disc levels from the C2-C3 to the C7-T1 for the cervical spine, and from L2 to S1 for the lumbar spine.	
Device Modification & Technological Characteristics:	The purpose of this 510(k) submission is to introduce additional configurations of cages in Titanium. The modified system has the same intended use and fundamental scientific technology as the previously-cleared system.	

Indications For Use:	The IVA Cage (ACIF, TI ACIF) are indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage The IVA Cage (PLIF, TLIF, DLIF, ALIF, Ti PLIF, Ti TLIF, Ti DLIF and Ti ALIF) are indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at one level of two continuous levels for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.
Performance Data:	The addition of components to the system did not introduce a new worst case construct as evaluated based on an engineering analysis. Dynamic axial compression test per ASTM F2077 was performed.
Predicate Device:	Primary predicate: IVA (ACIF, PLIF, TLIF, DLIF, and ALIF) Cage (K162220) - HUVEXEL Co., Ltd Additional predicate: SUSTAIN® & SUSTAIN® - R (K130478) - Globus Medical Inc.
Reference Device:	K121862 - Rex Anterior Cervical Plate System
Performance and SE Determination:	The **IVA CAGE Ti (ACIF, PLIF, TLIF, DLIF and ALIF)** have been demonstrated to be substantially equivalent to the predicate system(s) with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject device to the predicate device(s).