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

March 2, 2018

Ov World Co., Ltd
% Ho Dong Yang
CEO
Onbix Corporation
#821 Samil Plaza, 837 -26 Yeuksam-dong
Gangnam-gu, Seoul, South Korea 135-768

Re: K162366
Trade/Device Name: Omega Vl
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW
Dated: December 20, 2017
Received: January 3, 2018

Dear Ho Dong Yang:

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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K162366

Device Name
Omega V L

Indications for Use *(Describe)*
Omega V L comprised of PDO is indicated for use in soft tissue approximation where use of absorbable sutures is appropriate.

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.

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510(k) SUMMARY

This information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information: OV World Co., Ltd.
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Gasan digital 1-ro, Geumcheon-gu, Seoul, Korea

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Onbix Corporation
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Gangnam-gu, Seoul, 06253, Korea
Tel: *82-2-566-3360 / Fax: *82-2-6280-3360
Email: onbix@naver.com

Date Summary Prepared: Feb 15, 2018

Device Information:

Trade Name(s):	Omega V L
Classification Name:	suture, absorbable, polydioxanone
Panel:	general & plastic surgery
Product code:	NEW

Predicate Device Information:
K130191 MINT (Hansbiomed Corporation)

Device Description:
This device is made of polydioxanone and has bi-directional barbs along the long axis of the suture monofilament without needle attachment

Indications for Use
Omega V L comprised of PDO is indicated for use in soft tissue approximation where use of absorbable sutures is appropriate.

Comparison to Predicate Device(s):
This device is equivalent to the predicate devices in its intended use and technological characteristics, including:

* indications for use
* technological characteristics
* performance properties

Summary of the technological characteristics compared to the predicate device
The device is substantially equivalent to the predicate device in its technological characteristics stated in the comparison table provided below.

Comparison table is as follows:

Features	**Omega V L**	**MINT**
510(k) number	K162366	K130191
Product Classification	Absorbable polydioxanone surgical	Absorbable polydioxanone surgical suture
Manufacturer	OV World Co., Ltd	Hansbiomed Corporation
Intended use	general soft tissue approximation where use of an absorbable suture is appropriate	general soft tissue approximation where use of an absorbable suture is appropriate
Sterilization	EO gas	EO gas
Raw Material	PDO (supplier: Samyang)	PDO
Suture Characteristic	Synthetic Absorbable Monofilament	Synthetic Absorbable Monofilament
Technique of Deployment	Needles are not attached	Needles are not attached
Technical characteristic	Bi-directional barbs along the long axis of the suture monofilament without needle attachment	Bi-directional barbs along the long axis of the suture monofilament without needle attachment
Absorbable	Absorbable	Absorbable
Patient contact	Implant	Implant
Duration contact	Over 30 days	Over 30 days
Color additive	D&C Violet No.2	D&C Violet No.2
Suture diameters (USP)	1	1
Tensile strength	USP 2-0	USP 2-0

Non-Clinical Study Performance

1) Biocompatibility testing

Test	**Method**
Cytotoxicity	ISO 10993-5
Sensitization	ISO 10993-10
Acute Systemic Toxicity	ISO 10993-11
Irritation (Intracutaneous Reactivity)	ISO 10993-10
Material Mediated Pyrogenicity	ISO 10993-11
Mammalian Erythrocyte Micronucleus Test	ISO 10993-3
In Vitro Chromosomal Aberration Test	ISO 10993-3

Test	**Method**
Bacterial Reverse Mutation (Ames Test)	ISO 10993-3
Subchronic Systemic Toxicity	ISO 10993-11
Implantation	ISO 10993-6
Hemolysis	ISO 10993-4
LAL Endotoxin Test	USP <85>

2) Bench (performance) testing

Test
Absorption Test (non-barbed suture)
USP <861> Sutures—Diameter
USP <881> Tensile Strength
Barb Holding Strength
In Vitro Resorption Rate Test
In Vitro Tensile Strength Test

Conclusion
Based on the information provided in this summary, we conclude that Omega V L is substantially equivalent to the predicate device K130191.