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

November 22, 2016

Dongwon Medical Co., Ltd.
% Mr. Peter Chung
Plus Global
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K160761
Trade/Device Name: Dw-1c
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW
Dated: October 17, 2016
Received: October 24, 2016

Dear Mr. 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 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,

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)*
K160761

Device Name
DW-IC

Indications for Use *(Describe)*
The DW-1 C 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.

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510(k) Summary

[as required by 807.92(c)]

1. Applicant

1) Company : Dongwon Medical Co.,Ltd.
2) Address : 6F-601, 79-1, Mongnyeon-ro 153beon-gil, Gwangsan-gu, Gwangju, Korea
3) Tel : 82-62-430-6521
4) Fax : 82-62-430-6520
5) Contact person : Peter Chung, 412-687-3976
6) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
7) Submission date : Oct. 17, 2016

2. Device Information

1) Trade Name : DW-1C
2) Common Name : Absorbable polydioxanone surgical suture
3) Classification Name : Suture, Surgical, Absorbable, Polydioxanone
4) Product Code : NEW
5) Regulation Number : 21 CFR 878.4840
6) Class of device : Class II
7) Panel : General & Plastic Surgery

3. The legally marketed device to which we are claiming equivalence :

K130191 MINT

4. Device description :

DW-1C synthetic absorbable PDO suture is made of polydioxanone. The pigment for the violet dye is D&C Violet No.2. The DW-1C is available sterile after ethylene oxide (EO) gas sterilization and degrades or dissolves over time in tissue.

Each dyed (violet) suture has bi-directional barbs along the long axis of the suture monofilament without needle attachment. The DW-1C Synthetic Absorbable PDO suture approximate tissue, without the need to tie surgical knots, by using the opposing barbs on the surface to embed in the tissues after the surgeon precisely places the suture within the tissues.

While the formation of barbs in the DW-1C reduces the tensile strength relative to non-barbed suture material of the same size, tying of knots in non-barbed suture materials also reduce their effective strength. For this reason, the strength of the DW-1C can be compared with USP knot strength of non-barbed suture and the USP size of DW-1C is 1

5. Indication for Use :

DW-1C comprised of PDO is indicated for use in soft tissue approximation where use of absorbable sutures is appropriate.

6. Technological characteristics

DW-1C, absorbable polydioxanone surgical suture has the same fundamental scientific technology as the MINT, absorbable polydioxanone surgical suture, K130191.

7. Comparison of technological characteristics with the predicate device

The comparison of features and operation principles between DW-1C, absorbable polydioxanone surgical suture from Dongwon Medical Co., Ltd., and MINT, absorbable polydioxanone surgical suture from HansBiomed Corporation is listed as follows:

Proprietary	Submission Device	Predicate Device MINT, absorbable polydioxanone surgical suture, K130191	Substantially Equivalent or Not Substantially Equivalent
510(k) Number	N/A	K130191	N/A
Common Name	Absorbable polydioxanone surgical suture	Absorbable polydioxanone surgical suture	Substantially Equivalent
Trade name	DW-1C	MINT™	N/A
Manufacturer	Dongwon Medical Co.,Ltd.	HansBiomed Corporation	N/A
Product Classification	Absorbable polydioxanone surgical	Absorbable polydioxanone surgical	Identical
Indication for use	DW-1C comprised of PDO is indicated for use in soft tissue approximation where use of absorbable sutures is appropriate.	MINT comprised of PDO is indicated for use in soft tissue approximation where use of absorbable sutures is appropriate.	Identical
Raw Material	Polydioxanone suture, Samyang Corporation	Polydioxanone suture, Samyang Corporation	Identical
Suture Characteristic	Synthetic Absorbable Monofilament	Synthetic Absorbable Monofilament	Identical
Technique of Deployment	Needles are not attached	Needles are not attached	Identical
Technological Characteristic	Bi-directional barbs along the long axis of the suture monofilament	Bi-directional barbs along the long axis of the suture monofilament	Identical
Material	Polydioxanone	Polydioxanone	Identical
Sterilization	EO gas	EO gas	Identical
Size (USP)	1	1	Identical
Absorbable	Absorbable	Absorbable	Identical
Patient contact	Implant	Implant	Identical
Duration of contact	Over 30 Days	Over 30 Days	Identical
Braid/Monofilament	Monofilament	Monofilament	Identical
Number of barbs per linear length of suture	85	82	Similar
Barb shape	Cog shape	Cog shape	Identical
Barb size	0.567mm	0.601mm	Similar
Barb direction	A section and B section are opposite direction	A section and B section are opposite direction	Identical
Pattern of the barbs	bi-directional barbs along the long axis of the suture	bi-directional barbs along the long axis of the suture	Identical

Substantial equivalence summary

The DW-1C has a substantially equivalent intended use as the identified predicate, MINT comprised of PDO (Polydioxanone) manufactured by HansBiomed corporation and is made of polydioxanone intended for soft tissue approximation. The subject and predicate are composed of the same material (PDO) and

have bi-directional barbs, and have the same indications for use.

8. Performance data:

Laboratory testing regarding characteristics was performed on the DW-1C to verify its safety and performance. A biocompatibility assessment was performed on the patient contact materials of DW-1C.

1) Biocompatibility test

Test Identification	Method	Criteria	Result PASS/FAIL	Report
Cytotoxicity MEM Elution Method (Cytotoxicity)	ISO10993-5 Tests for Cytotoxicity, in vitro Methods	No evidence of causing cell lysis or toxicity to fibroblast cells	Not Cytotoxic (PASS)	R-C-R-8400
ISO Guinea Pig Maximization Sensitization Test (Sensitization)	ISO10993-10 Test for Irritation and sensitization 6.2 Maximization sensitization test	No delay in dermal contact sensitization	No evidence SC and CSO extracts causing delayed dermal contact sensitization (PASS)	R-C-R-8400
ISO Acute Intracutaneous Reactivity Study in the Rabbit (Intracutaneous Test)	ISO10993-10 Test for Irritation and sensitization 5.4 Intracutaneous reactivity test	No irritation	Primary Irritation Index Characterization SC extract = 0.0 CSO extract = 0.0 (PASS)	R-C-R-8400
ISO Systemic Toxicity Study in Mice (Acute systemic toxicity)	ISO10993-11 Tests for systemic toxicity	No reaction No Mortality during this study or evidence of systemic toxicity	No Mortality or Evidence or Significant Systemic toxicity (PASS)	R-C-R-8400
Bacterial Reverse Mutation study (Ames test)	ISO 10993-3 Test for Genotoxicity, Carcinogenicity and Reproductive Toxicity.	Tester strain char must exhibit sensitivity to crystal violet, UV, no growth biotin plates and growth histatine-biotin plates…number of mutation revertants (including spontaneous reversions) statistically less than negative control results	The Saline and dimethyl sulfoxide test article extracts were considered to be non-mutagenic to Salmonella typhimurium and Escherichia coli tester strains. (PASS)	R-C-R-8400
Genotoxicity : In Vitro Chromosomal Aberration.	EN ISO 10993-3 Test for Genotoxicity, Carcinogenicity and Reproductive Toxicity.	Whether the extract would cause genotoxicity in Chinese Hamster Ovary cells	Not considered genotoxic (Pass)	R-C-R-8400
Mouse Bone Marrow Micronucleus	EN ISO 10993-3 Test for Genotoxicity, Carcinogenicity and Reproductive Toxicity.	No cellular toxicity	Not considered to be genotoxic (Pass)	R-C-R-8400
4 Week Subchronic Toxicity	ISO10993-11 Tests for systemic toxicity	No signs of behavioral change or toxicity in rats	No significant evidence of systemic toxicity from the subcutaneous implantation of the test	R-C-R-8400

			article into rats.(Pass)	
ISO Muscle Implantation Study in Rabbits, 12 Weeks (Implantation)	ISO 10993-6 Test for Local Effect After Implantation.	No significant macroscopic and microscopic reactions nonirritant compared to USP Negative Control Implant Material	Macroscopic reaction for the test article device was not significant as compared to the USP negative control implant material (PASS)	R-C-R-8400

Based on the above testing results, the DW-1C is biocompatible.

2) Bench (performance) testing

In the following table, the summary of all the bench tests is provided.

No.	Title	Result summary	File (Protocol/ Report)
1	USP 32:2009 Absorbable Surgical Suture	In vivo absorption of absorbable suture were observed at 10, 80, 120, 220days after implantation. Absorption time of MONOSORB was 180-220days	R-C-R-83e
2	Dimension Test USP 37-NF 32:2014 <861> Sutures - Diameter	Acceptance Criteria for this testing ±5% No failed results were performed in any DW-1C during the performing period.	BTR 15-11
3	Tensile Strength USP 37-NF 32: 2014 <881>Tensile Strength	Acceptance Criteria for this testing Not less than 300gf. No failed results were performed in any DW-1C during the performing period.	BTR 15-11
4	Holding forces	There was no significant difference between test samples and reference samples	16-KE-126
5	Weights	The weights of test samples in 1st (G1, Week 2), 2nd (G2 , Week 4), 3rd (G3, Week 6), 4th (G4 , Week 8), 5th (G5, Week 10), 6th (G6, Week 12) and 7th (G7, Week 14) necropsy groups were statistically significantly lower than that of the test samples in before implantation ($p<0.001$).	16-KE-126
6	Biodegradation (absorption rate)	The biodegradation levels of test samples in 1st, 2nd, 3rd, 4th, 5th, 6th and 7th necropsy groups were significantly lower than that of the test samples in before implantation ($p<0.001$).	16-KE-126
7	Mechanical property (Tensile strengths)	The tensile strengths of test samples in 3rd, 4th, 5th and 6th necropsy groups were significantly lower than that of test samples in 1st necropsy group ($p<0.05$, $p<0.05$, $p<0.05$ and $p<0.01$). In case of 7th necropsy groups, the test samples were degraded into small particles, so it was not possible to measure the tensile strengths.	16-KE-126
8	Endotoxin test	Endotoxin concentration of the test sample is less than 0.1EU/device.	CT16-074111
9	Pyrogen test	There was non-pyrogenicity to the extraction solution.	CT16074112

Safety and performance

Testing was performed per FDA's Class II Special Controls Guidance Document : Surgical Sutures, including testing in accordance with the USP monograph for absorbable sutures, in vitro and in vivo resorption testing, biocompatibility testing in accordance with ISO 10993, and a barb holding strength evaluation.

Holding forces, Weights, Biodegradation (absorption rate), Mechanical property (Tensile strengths), Endotoxin test and Pyrogen test were performed.

No failed results were noted in any product evaluations. The test results satisfied all the acceptance

criteria.

9. Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification MINT™ comprised of PDO(Polydioxanone) (K130191) concludes that the DW-1C is substantially equivalent to predicate device as described herein.