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

June 2, 2015

Dong Il Technology Ltd.
c/o Mr. Peter Chung
Plus Global
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K150076
Trade/Device Name: Sonic Surgeon 310L, Sonic Surgeon 600L and Sonic Surgeon 800L
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZI
Dated: April 29, 2015
Received: April 30, 2015

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,

for 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

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)*
K150076

Device Name
Sonic Surgeon 310L, Sonic Surgeon 600L and Sonic Surgeon 800L

Indications for Use *(Describe)*
Sonic Surgeon 310L, Sonic Surgeon 600L and Sonic Surgeon 800L are piezoelectric devices for surgery that enable mechanical ultrasound treatment, osteotomy and osteoplasty techniques to be applied in dental use.

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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K150076

510(k) Summary[as required by 807.92(c)]

A. Submission Information

1) Submission: 510(k) Submission
2) Submission Date: June 1, 2015
3) Submission Type: Traditional
4) 510(k) number: K150076

B. Applicant:

1) Company name: DONG IL TECHNOLOGY LTD.
2) Address: 28, Namyang-ro, 930(gubaeksamsip)beon-gil, Bugyang-dong, Hwaseong-si, Gyeonggi-do, Republic of Korea
3) Tel: +82(31)229-5500
4) Fax: +82(31)357-2610
5) Homepage: http://www.dit-med.co.kr
6) Contact person: Peter Chung 412-687-3976
7) Contact person address: 300, Atwood ST, Pittsburgh, PA, 15213

C. Proprietary and Established Names:

1) Trade Name: Sonic Surgeon 310L, Sonic Surgeon 600L and Sonic Surgeon 800L
2) Common Name: Bone cutting instrument and accessories
3) Regulation Name: Sonic surgical instrument and accessories/attachments
4) Regulation Number: 872.4120
5) Classification: Class 2
6) Panel: Dental
7) Product Code: DZI
8) Identify contact classification:
   Category: External communicating device
   Contact: Tissue/bone/dentin
   Contact duration: Limited exposure (A)

D. legally marketed predicate devices:

Primary: Sonic Surgeon 300 (K110881)

Reference: UBS ultrasonic bone surgery and UDD ultrasonic debridement device (K080220)

E. Device Description:

Sonic Surgeon 310L, Sonic Surgeon 600L and Sonic Surgeon 800L are ultrasonic surgical units intended for mechanical ultrasound treatment in prophylaxis, periodontics or endodontics. The normal mode is tooth scaling applications, and the Boost Mode of Sonic Surgeon 310L, Sonic Surgeon 600L and Sonic Surgeon 800L can be used for surgical procedures, including osteotomy, osteoplasty, periodontal surgery and implantation.
The tips can easily be changed during the treatment and must also be cleaned and autoclaved.
Materials for Sonic Surgeon 310L, Sonic Surgeon 600L and Sonic Surgeon 800L are as follows:

Component	Material
Enclosure (Generator Unit, Foot Switch)	PC(Polycarbonate) ABS(Acrylonitrile-Butadiene-Styrene Terpolymer)
Hose, and seals	Silicone
Enclosure (Handpiece)	PES(Polyethersulfone)
Tip	PPSU(Polyphenylsulfone)

F. Intended use

Sonic Surgeon 310L, Sonic Surgeon 600L and Sonic Surgeon 800L are piezoelectric devices for surgery that enable mechanical ultrasound treatment, osteotomy and osteoplasty techniques to be applied to use.

G. Technological Characteristics:

Sonic Surgeon 310L, Sonic Surgeon 600L and Sonic Surgeon 800L have the following features:

- Sonic Surgeon 310L, Sonic Surgeon 600L and Sonic Surgeon 800L transform generated ultrasonic (26±3kHz) energy to the kinetic energy and transmits it to the tip.
- The generator of the Sonic Surgeon 310L, Sonic Surgeon 600L and Sonic Surgeon 800L performs automatic tuning of the operating frequency, the efficiency of the piezoelectric transducer in the handpiece. This feature makes it possible to perform bone cutting, grinding and drilling action.

Our device is very similar to predicate devices, Sonic Surgeon 300 (K110881), UBS ultrasonic bone surgery and UDD ultrasonic debridement device(K080220), because Sonic Surgeon 310L, Sonic Surgeon 600L and Sonic Surgeon 800L have the following equivalent characteristics: intended use, sterilization method, material used, electrical input power, frequency, and power output as predicate devices.

Summary Comparison table

Manufacturer	Model	Insulation Class	Input Power			Ultrasonic Operation Frequency
			Input Voltage	Current or Power	Frequency	
K150076						
DONG IL TECHNOLOGY LTD	Sonic Surgeon 310L, 600L, 800L	Class I, Type B	AC 100–240 V	AC Max 2A	50 / 60 Hz	Automatic scanning, 26 ± 3 KHz
K110881						
DONG IL TECHNOLOGY LTD	Sonic Surgeon 300	Class I, Type B	AC 95–115 V AC 210–240 V	AC Max 1A	50 / 60 Hz	Automatic scanning, 26 ± 3 KHz
K080220						
ITALIA MEDICA S.R.L	UBS ultrasonic bone surgery and UDD ultrasonic debridement device	Class I, Type CF	AC 230V±10%	140 VA	50 / 60 Hz	26 kHz ± 10%

Manufacturer	Model	Indications for Use
K150076		
DONG IL TECHNOLOGY LTD	Sonic Surgeon 310L Sonic Surgeon 600L Sonic Surgeon 800L	Sonic Surgeon 310L, Sonic Surgeon 600L, Sonic Surgeon 800L are piezoelectric devices for surgery that enable mechanical ultrasound treatment, osteotomy and osteoplasty techniques to be applied in dental use.
K110881		
DONG IL TECHNOLOGY LTD	Sonic Surgeon 300	Ultrasonic Surgical Unit is a piezoelectric device for bone surgery that enables osteotomy and osteoplasty techniques to be applied to in dental use.
K080220		
ITALIA MEDICA S.R.L	UBS ultrasonic bone surgery and UDD ultrasonic debridement	The UBS Ultrasonic Bone Surgery and the UDD Ultrasonic Debridement Device are bone cutting instruments intended for use in oral surgery.

(1) Comparison between proposed Device and predicate ***Sonic Surgeon 300(K110881)***

	Predicate Device	**Proposed Device**			**remark**
Model Name	Sonic Surgeon 300	Sonic Surgeon 310L	Sonic Surgeon 600L	Sonic Surgeon 800L	
Features					
LED Light	X	O	O	O	
LCD	LCD Display	Touch LCD	Touch LCD	Touch LCD	
Input Voltage	AC 95 - 115V (50/60Hz) AC 210 – 240 V (50/60Hz)	AC100V - AC240V (50/60Hz)	AC100V - AC240V (50/60Hz)	AC100V - AC240V (50/60Hz)	
Pump Cover	Automatic	Manual	Manual	Manual	
Power Supply	Toroidal Transformer	SMPS	SMPS	SMPS	
Foot Switch IP class	IPX1	IPX8	IPX8	IPX8	
Operating Frequency	26 ± 3 ㎑	26 ± 3 ㎑	26 ± 3 ㎑	26 ± 3 ㎑	
Other features are same as Predicate.					
Dimensions					
Hand piece	A type: Ø 20×154.2mm(L)	A type: Ø 20×154.2mm(L) B type(LED): Ø 20×152.7mm(L)	C type(LED): Ø 22.5×155.4mm(L)	C type(LED): Ø 22.5×	
Generator	H:106mm L:300mm W:284mm	H:106mm L:300mm W:298m	H:106mm L:300mm W:298mm	H:106m m L:300m	
Foot Switch	H: 37 mm L: 140 mm W: 240 mm	H: 37 mm L: 140 mm W: 240 mm	H: 37 mm L: 140 mm W: 240 mm	H: 37 mm L: 140 mm W: 240 mm	
Tip Holder	H: 37.9 mm L: 41 mm W: 58 mm	H: 38 mm L: 41 mm W: 58 mm	H: 38 mm L: 41 mm W: 58 mm	H: 38 mm L: 41 mm W: 58 mm	
Torque Wrench	Ø 40×31mm(L)	Ø 40×31mm(L)	Ø 40×31mm(L)	Ø 40×31mm(L)	
Wire Water Pack	Ø 5×477mm(L)	Ø 5×470mm(L)	Ø 5×470mm(L)	Ø 5×470mm(L)	
Storage tray-not for sterilizer use	H: 61 mm L: 180 mm W: 200 mm	H: 61 mm L: 180 mm W: 200 mm	H: 61 mm L: 180 mm W: 200 mm	H: 61 mm L: 180 mm W: 200 mm	
Wire Hand piece	H: 128 mm L: 66 mm W: 83 mm	H: 128 mm L: 66 mm W: 83 mm	H: 128 mm L: 66 mm W: 83 mm	H: 128 mm L: 66 mm W: 83 mm	
Tips	Refer to Table 4				Table.1
Materials					
Refer to Table 5 & Table 6 The material of handpiece enclosure is different from Sonic Surgeon 300. Other materials are same as predicate device.					
Performance parameters					
LED Light Control	X	O	O	O	Table.2
Output Power	MAX 40W	15 ~ 50W	15 ~ 70W	15 ~ 90W	Table.3
Irrigation	10~90 ml/min.	7~110 ml/min.	7~110 ml/min.	7~110 ml/min.	Table.4

(2) Comparing ***'output Power'*** between proposed Device and predicate model ***'*UBS ultrasonic bone surgery and UDD ultrasonic debridement device *(K080220)'***

	Predicate Device	**Proposed Device**			**remark**
Manufacturer	ITALIA MEDICA S.R.L	DONG IL TECHNOLOGY LTD.			
Model Name	Model Ultrasonic Debridemen t	Sonic Surgeon 310L	Sonic Surgeon 600L	Sonic Surgeon 800L	
Performance parameters					
Output Power	90 W	30~50 W	50~70 W	70~90 W	Table.3

Table.1 Tips (Sonic Surgeon 300/310L/600L/800L)

No.	**Sonic Surgeon 300 / 310L**		**Sonic Surgeon 600L / 800L**	
	Name	**Size**	**Name**	**Size**
1	DG3-001	Ø 4.5×28.26mm(L)	BTG-B017	Ø 5.5×28.5mm(L)
2	DG3-002	Ø 4.5×30.51mm(L)	BTG-R018	Ø 5.5×29.5mm(L)
3	DM3-003	Ø 4.5×31.86mm(L)	BTM-D019	Ø 5.5×31.5mm(L)
4	DE3-004	Ø 4.5×28.29mm(L)	BTE-K020	Ø 5.5×29.0mm(L)
5	DH6-005	Ø 4.5×30.75mm(L)	BTH-S021	Ø 5.5×30.1mm(L)
6	DD6-016	Ø 4.5×27.7mm(L)	BTD-F022	Ø 5.5×27.5mm(L)
7	DD6-028i	Ø 4.5×28.2mm(L)	BTD-F023	Ø 5.5×28.5mm(L)
8	DC6-Saw	Ø 4.5×31.5mm(L)	BTC-I024	Ø 5.5×31.5mm(L)
9	DC6-Saw L	Ø 4.5×30.9mm(L)	BTC-I025	Ø 5.5×31.0mm(L)
10	DC6-Saw R	Ø 4.5×30.9mm(L)	BTC-I026	Ø 5.5×31.0mm(L)

Table.2 LED Brightness

LED level	**LED brightness (lux)**			**Remark**
	Sonic Surgeon 310L	Sonic Surgeon 600L	Sonic Surgeon 800L	
1	1,900±100	2,000±100	2,000±100	Distance: 20mm
2	2,400±100	2,500±100	2,500±100	
3	2,600±100	2,800±100	2,800±100	

Table.3 Output Power

[Unit: W]

Model Name	Normal Mode			Boost Mode		
	Level1	Level2	Level3	Level1	Level2	Level3
Sonic Surgeon 310L	15~17	17~21	21~27	30~50	30~50	30~50
Sonic Surgeon 600L	15~17	17~21	21~27	50~70	50~70	50~70
Sonic Surgeon 800L	15~17	17~21	21~27	70~90	70~90	70~90

Table.4 Water flow

Pump level	Water flow (ml/min approximately)		Remark
	Sonic Surgeon 300	Sonic Surgeon 310L/600L/800L	
1	10	7 ~ 13	
2	30	15 ~ 40	
3	50	40 ~ 60	
4	70	60 ~ 80	
5	90	80 ~ 110	

Table.5 Materials (Sonic Surgeon 300)

No	Name	Materials	Company	CAS No.	Grade
1	Enclosure (Generator Unit)	PC(Polycarbonate) ABS(Acrylonitrile-Butadiene-Styrene Terpolymer)	LG Chemical	PC (103598-77-2) / ABS (9003-56-9)	LUPOY GN5001RF
2	Hose, and seals	Silicone	Elkem	7440-21-3	Synthetic rubber
3	Enclosure (Hand Piece)	PES (Polyethersulfone)	BASF	25608-63-3	Ultrason E2010
4	Tips	TrimRite stainless	CARPENTER	-	UNS S42010
5	Tip Coating	ZrN (Zirconium Nitride)	Chemetall (Zirconium)	25658-42-8	CA
		ZrN+Diamond	ProSciTech	Diamond (77820-40-3)	M24

Table.6 Materials (Sonic Surgeon 310L/600L/800L)

No	Name	Materials	Company	CAS No.	Grade
1	Enclosure (Generator Unit)	PC(Polycarbonate) ABS(Acrylonitrile-Butadiene-Styrene Terpolymer)	LG Chemical	PC (103598-77-2)	LUPOY GN5001RF
				ABS (9003-56-9)	
2	Hose, and seals	Silicone	Elkem	7440-21-3	Synthetic rubber
3	Enclosure (Hand Piece)	PPSU (Polyphenylsulfone)	Solvay	Polyphenylsulfone (25608-64-4)	Duradex D-3000
				Titanium dioxide (13463-67-7)	
				Carbon black (1333-86-4)	
4	Tips	TrimRite stainless	CARPENTER	-	UNS S42010
5	Tip Coating	ZrN (Zirconium Nitride)	Chemetall (Zirconium)	25658-42-8	CA
		ZrN+Diamond	ProSciTech	Diamond (77820-40-3)	M24

H. Performance Information

The Sonic Surgeon 310L, Sonic Surgeon 600L and Sonic Surgeon 800L have been manufactured and tested to meet the safety requirements of several IEC standards. The Sonic Surgeon 310L, Sonic Surgeon 600L and Sonic Surgeon 800L comply with IEC 60601-1 Medical electrical equipment - Part 1: General requirements for safety and IEC 60601-1-2:2007, Medical electrical equipment - Part 1: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.

I. Conclusion:

The performance tests and evidence demonstrate that Sonic Surgeon 310L, Sonic Surgeon 600L and Sonic Surgeon 800L function in a substantially equivalent manner to the predicate device.

In terms of output power, Sonic Surgeon 310L, Sonic Surgeon 600L and Sonic Surgeon 800L are substantially equivalent to the predicate device UBS ultrasonic bone surgery and UDD ultrasonic debridement device (K080220). The maximum output power of Sonic Surgeon 800L is 70~90W and that of UBS ultrasonic bone surgery and UDD ultrasonic debridement device (K080220)' is 90W. In terms of light power, the capacity of the device's LED light is demonstrated in 'Biocompatibility' section and an LED report was attached as evidence.

Because our proposed device has the same intended use, the same sterilization method, same materials used, same electrical input power, same frequency, and same power output as predicate devices, as well as similarity of product configuration and administration, it can be concluded the Sonic Surgeon 310L, Sonic Surgeon 600L and Sonic Surgeon 800L are substantially equivalent to the identified predicate devices.