BraunSolutions
% Mr. Alexander Henderson
Official Correspondent
970 South Dawson Way
Unit 14
Aurora, Colorado 80012-3827

Re: K173359
Trade/Device Name: BIOXEL Fractional CO2 Surgical Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX, ONG
Dated: June 1, 2018
Received: June 5, 2018

Dear Mr. Henderson:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173359

Device Name
BIOXEL CO2 Surgical Laser System

Indications for Use *(Describe)*
The BIOXEL CO2 Surgical Laser System is indicated for use, in the non-fractionated mode, for Incision, Excision, Ablation, Vaporization, and Coagulation of Human Body Soft Tissues. The system is intended for use in Dermatology, Plastic and General Surgery, Neurosurgery, and Podiatry.

The BIOXEL CO2 Surgical Laser System is indicated for use, in the fractionated mode, for Ablative Skin Resurfacing, Wrinkle, Fine line, Rhylides, and Furrows in Dermatology.

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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K173359

AMI INC.

RM. 1412, SJ TECHNO VILLE, 278, BEOTKKOT-RO, GEUMCHEON-GU, SEOUL, KOREA

TEL : 82-2-3281-9091 FAX : 82-2-3281-8011 E-MAIL : amimed@amimed.co.kr

EXECUTIVE SUMMARY

1. Name of Device

Trade/Device Name: BIOXEL Fractional CO2 Surgical Laser System

Regulation Number: 21CFR 878.4810

Regulation Name: Powered Laser Surgical Instrument

Regulation Description: Laser Surgical instrument for use in general and plastic surgery and dermatology.

Device Class: II

Product Code: GEX

2. Predicate Devices

K111831 MX-7000 MICROXEL, Dae Shin Enterprises

K180036 SMAXEL, IDS, Ltd.

3. **Prior Submissions Statement**

There were no prior submissions for the BIOXEL Fractional CO2 Surgical Laser System.

4. Device Description

The BIOXEL CO2 Surgical Laser System is used in Dermatology, Plastic and General Surgery, Neurosurgery and Podiatry.

This equipment consists of main body, Articulated Arm, hand-piece, protective goggles, foot switch and power cable. In a main body, there are a monitor displaying all information needed by an operator at a glance and a touch LCD screen, which facilitates operation of this equipment at user's convenience. The laser output is initiated with the foot switch.

5. Indications for Use

The BIOXEL CO2 Surgical Laser System is indicated for use, in the non-fractional mode, for Incision, Excision, Ablation, Vaporization, and Coagulation of Human Body Soft Tissues. The system is intended for use in Dermatology, Plastic and General Surgery, Neurosurgery and Podiatry.

The BIOXEL CO2 Surgical Laser System is indicated for use, in the fractional mode, for Ablative Skin Resurfacing, Wrinkle, Fine line, Rhylides, and Furrows in Dermatology.

6. Comparison Chart to Predicate Devices

Characteristics	BIOXEL (AMI, Inc.) Subject Device	SMAXEL (IDS, Ltd.) K180036	MICROXEL (Dae Shin) K111831
Laser Wavelength	10,600nm	10,600nm	10,600nm
Laser Type	CO_2	CO_2	CO_2
Maximum Power	40W	40W	40W
Laser Transfer Method	Articulated Arm with hand piece	Articulated Arm with hand piece	Articulated Arm with hand piece
Dimensions(mm)	440 x 480 x 1,830	420 x 410 x 920	420 x 410 x 1,120
Weight	50 kgs	50 kgs	45 kgs
Energy	1-30 mJ	5-30 mJ	4-30 mJ

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Density	1-23 Level	1-23 Level	1-23 Level
Scan Size	20 x 20 mm	20 x 20 mm	5 x 15 mm
Scan Shape	Square, Hexagonal, Triangular, Circular	Square, Hexagonal, Triangular, Circular	Square, Circle
Mode	Fractional Mode General (CW, Normal Pulse, Super Pulse, Ultra Pulse)	General, Fractional, Non-Factional, Low Power Fractional	Fractional Mode Normal Mode(CW, Super Dream Pulse, Ultra Dream Pulse)
Off Time	0.2 ~ 2.5 sec, Single	0.5 ~ 2.5 sec, Single	0.5 ~ 1.5 sec, Single

8. Summary of Performance Testing

The BIOXEL performs as intended based on performance data provided in the submission.

Software: Verification and validation testing of the software confirm that the software version is appropriate for release.

Electrical Safety and Electromagnetic Compatibility: The BIOXEL has been tested for electromagnetic compatibility and electrical safety per the applicable recognized consensus standards (IEC 60601-1, IEC 60601-1-2, IEC 60601-2-22 and IEC 60825-1).

Biocompatibility: Biocompatibility of the patient contacting components of the device has been established per ISO 10993-5.

9. Conclusion

The BIOXEL CO2 Surgical Laser System was found to be substantially equivalent to the predicate devices.

The BIOXEL CO2 Surgical Laser System shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to the predicate devices.