IDS, Ltd.
% Alexander Braun Henderson
Official Correspondent
BraunSolutions
970 South Dawson Way Unit 14
Aurora, Colorado 80012

October 5, 2018

Re: K181868
Trade/Device Name: SHINY RPL 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: ONF
Dated: July 12, 2018
Received: July 12, 2018

Dear Alexander Braun 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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,

Neil R Ogden -S
2018.10.05 14:13:19 -04'00'

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)*
K181868

Device Name
SHINY RPL System

Indications for Use *(Describe)*
The IDS SHINY IPL system is intended for use in Surgical, Aesthetic and Cosmetic applications in Dermatology by using filtered Intense Pulsed Light to treat the following conditions with different wavelengths to skin types I-IV.

Wavelengths:	Conditions:
415nm - 950nm	Acne, Vulgaris
560nm - 950nm	Melasma, Ephelides
640nm - 950nm	Acne, Hair Reduction
640nm - 1200nm	Hair Reduction
695nm - 1200nm	Hair Reduction
755nm - 1200nm	Hair Reduction

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

1. Name of Device:

Trade/Device Name: SHINY IPL System
Regulation Number: 21CFR 878.4810
Regulation Description: Laser surgical instrument for use in general and plastic surgery and dermatology.
Review Panel: General and Plastic Surgery
Device Class: II
Product Code: ONF

2. Predicate: K102857 R2PL System, Ahwon Medi Instrument

3. Prior Submissions: There were no prior submissions for the SHINY IPL System.

4. **Device Description:**

The SHINY IPL System, using visible rays created by Xenon Lamp through Sapphire which are installed on Hand-piece, and composed Main board, LCD screen, Hand-piece, Cooling system. This device uses computer controlled power supply and filter to generate visible ray pulses of prescribed duration and intensity. This device also equipped the Cooling systems to maintain both the Treatment head / Systems at appropriate and safe temperatures.
The visible ray pulses or emission spectra provide therapeutic indications relevant to specific wavelengths emitted from the system. This system has two hand-pieces and each hand-piece has 3 wavelengths to choose from at the end of the Hand-piece there is a sapphire filter. Visible rays are emitted when the button is pressed.

5. Intended Use:

The IDS SHINY IPL system intended for use in Surgical, Aesthetic and Cosmetic applications in Dermatology by using filtered Intense Pulsed Light to treat the following conditions with different wavelengths to skin types I-IV.

Wavelengths:	**Conditions:**
415nm - 950nm	Acne, Vulgaris
560nm - 950nm	Melasma, Ephelides
640nm - 950nm	Acne, Hair Reduction
640nm - 1200nm	Hair Reduction
695nm - 1200nm	Hair Reduction
755nm - 1200nm	Hair Reduction

6. Comparison to Predicate Device:

Characteristics	SHINY IPL SYSTEM (IDS LTD.) Proposed Device	R2PL (Ahwon Medi Instrument) K102857 Predicate
Laser Wavelengths	415nm-950nm 560nm-950nm 640nm-950nm 640nm-1200nm 695nm-1200nm 755nm-1200nm	415nm-950nm 560nm-950nm 590nm-1200nm 640nm-1200nm 695nm-1200nm
Lamp Type	Xenon Gas	Xenon Gas
Light Type	Intense Pulsed Light	Intense Pulsed Light
Light Transfer Method	Hand-piece	Hand-piece
Spot Size	14.3 x 42.6mm	10.0 x 34.0mm
Fluence	5-40J/cm2	5-40J/cm2
Pulse Duration(On Time)	2.0-35.0ms	2.0-35.0ms
Pulse Delay(Off Time)	3.0-60.0ms	3.0-60.0ms
Repetition Rate	1, 3, 5Hz	1Hz

7. Summary of Performance and Safety Testing:

The SHINY IPL System performs as intended based on performance data provided in this submission.

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

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

8. Conclusion:

The SHINY IPL System was found to be substantially equivalent to the predicate devices and shares the same or similar indications for use, design, operational and functional features as the predicate devices.