



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

April 22, 2016

Bison Medical Co Ltd  
% Young Chi  
President  
Bio-med Usa Inc  
27 New England Drive  
Ramsey, New Jersey 07446

Re: K160227

Trade/Device Name: Accento / HWA Dual/single Laser

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

Dated: January 25, 2016

Received: January 29, 2016

Dear Young Chi:

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

## Indications for Use

510(k) Number (if known )

**K160227**

Device Name

**ACCENTO Single laser**

Indications for Use (Describe)

The ACCENTO single laser system is indicated for the following:

755 nm Long pulsed Alexandrite laser

Temporary hair reduction, Stable long-term or permanent reduction through selective targeting of melanin in hair follicles.

Treatment of benign pigmented lesions. Treatment of Winkles. The photocoagulation of dermatological vascular lesions ( such as port of wine stains, hemangiomas, telangiectasias)

Permanent hair reduction is defined as the long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.

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.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov

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## Indications for Use

510(k) Number (if known)  
K160227

Device Name

ACCENTO Dual Laser System

Indications for Use (Describe)

The ACCENTO combined laser system is indicated for the following:

**755 nm Long pulsed Alexandrite laser**

Temporary hair reduction, Stable long-term or permanent reduction through selective targeting of melanin in hair follicles.

Treatment of benign pigmented lesions. Treatment of Winkles. The photocoagulation of dermatological vascular lesions ( such as port of wine stains, hemangiomas, telangiectasias)

**1064nm Long pulsed Nd:YAG laser**

the removal of un-wanted hair reduction, for stable long term or permanent hair reduction and for treatment of PFB to all skin type Fitzpatrick I-VI including tanned skin. Treatment of Photocoagulation and hemostasis of pigmented and vascular lesions such as port wine stain, hemangioma, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. Coagulation and hemostasis of soft tissue, Benign pigmented lesions such as lentigos (age spot) Solar lentigos ( sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae skin tags, keratoses, tattoo reduction (dart color) and plaques. Pigmented lesions to reduce lesion size and patients with lesions, reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of scar, Treatment of wrinkle.

Permanent hair reduction is defined as the long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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## 510 (K) Summary

As required by CFR 807.92(c), traditional

### 1. Manufacturer.

Feb 22 2016

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RegNr: 3011555967

### 2. Submitter and Contact person

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 Young Chi, President.  
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### 3. Name of Device

Trade name	:	ACCENTO Dual / Single
Classification name :	:	Powered, Laser surgical instrument
Common name	:	Alexandrite and Nd:YAG long pulse laser
Regulation	:	878.4810 Class II
Classification Panel	:	General and Plastic Surgery.
Product Code	:	GEX

### 4. Legally marketed Predicate Device

K130199 CLARITY LPC Alexandrite and Nd:YAG Combined laser Lutronic Corp

ACCENTO Alexandrite and Nd: YAG Long pulsed combined laser system is produced same two wave length (755nm and1064nm ), with same characteristics such as Design, Construction, Energy rate, Pulse Duration, optical fiber hand piece, Cooling system and intended use as already cleared predicate device K130199 by Lutronics,

### 5. Device Description

The ACCENTO Dual device are contained two separate laser heads 755nm long pulsed Alexandrite and 1065nm Nd: YAG laser. The output of each laser head is optically combined on the laser rail to delivery same beams path. This single delivery system can obtain either 755nm or 1064nm wavelengths.

The LED touch screen equipped in Control panel to adjust parameters easily Each laser heads has self contained circulation water system to cool system and laser head fully using distilled water at a controlled temperature. The ACCENTO laser system delivers laser energy with various pulse durations from 0.2ms to 350ms. The output of this laser is delivered to the area of treatment by means of lens coupled user replaceable optical fiber with a treatment handpiece attached to its distal end.

A trigger switch( Finger or Foots pedal) is used to control the delivery of laser pulse. The user may choose to deliver a single pulse each time the trigger switch is depressed, or pulses may be deliver repetitively as long as the switch is depressed at repetition rates up to 10 pulses per second depending on the chosen pulse duration Energy from the laser is directed to the target area via optical fiber handpiece.

The Dynamic Cooling system provides a short burst of Cryogen spray prior to firing the laser pulse, The Energy is delivered via optical fiber to handpiece with a spot size 2, 3, 5, 8,10,12,18, 20mm diameter circular beam on the skin. Operator may select parameters as desired fluence and repetition rate, and operated using touch screen and display panel

This device consist of

- Power supply and modulator system
- Optical laser Hand pieces and delivery system
- Circulator system
- Software control system, Dynamic cooling system,
- LED control panel

ACCENTO single device are contained 750nm Alexandrite laser only, and provided it optionally to treat related indication.

This device also equipped with safety interlock systems to protect patients and user

## 6. Performance test

Clinical and Non-Clinical performance test data was not provided in this submission. But, manufactured in accordance with both mandatory and voluntary standard

IEC60601-1 part 1 : General requirement for basic safety and essential performance.

IEC60601-1-2: 2007 Electro Magnetic Compatibility test

IEC60601-2-22 Part 2, Particular requirements for safety of diagnostic and Therapeutic laser

IEC60825-1 :2nd ED, Equipment classification and requirement.

## 7. Indication for use

The ACCENTO combined laser system is indicated for the following:

755 nm Long pulsed Alexandrite laser

Temporary hair reduction, Stable long-term or permanent reduction through selective targeting of melanin in hair follicles.

Treatment of benign pigmented lesions. Treatment of Winkles. The photocoagulation of dermatological vascular lesions ( such as port of wine stains, hemangiomas, telangiectasias)

1064nm Long pulsed Nd:YAG laser

the removal of un-wanted hair reduction, for stable long term or permanent hair reduction and for treatment of PFB to all skin type Fitzpatrick I-VI including tanned skin.

Treatment of Photocoagulation and hemostasis of pigmented and vascular lesions such as port wine stain, hemangioma, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. Coagulation and hemostasis of soft tissue, Benign pigmented lesions such as lentigos (age spot) Solar lentigos ( sun spots), cafe au lait macules, seborrheic keratoses, nevi, Chloasma, verrucae skin tags, keratoses, tattoo reduction (dart color) and plaques.

Pigmented lesions to reduce lesion size and patients with lesions, reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of scar, Treatment of wrinkle.

Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, 12, months after the completion of a treatment regime

## **8. Biocompatibility, Sterilization**

This device are non-contacted mode.

Hand piece tips is made by same material as predicate device.

## **9. Conclusion.**

ACCENTO Dual / Single combined laser system, in this submission, is substantially equivalent to several already cleared predicate device in respect to the Intended use, Main function, Technology, Principal operation and performance.

And every Safety test report show it as safe and effective as predicate device and it does not raise any additional issues for safety and effectiveness.

Bison Medical Co., Ltd will update and include in this summary any other information deemed seasonally necessary by the FDA