



February 28, 2018

Cosmo Far East Technology Limited
% Rain Yip
Registered Engineer
Feiyong Drug & Medical Consulting Technical Service Group
Rm. 3005, Area B, Bldg.1, Southward Ruifeng Business Center
Guimiao Road
Shenzhen, 518000 Cn

Re: K173678

Trade/Device Name: Diode Laser Cap
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: November 21, 2017
Received: November 30, 2017

Dear Rain Yip:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Jennifer R. Stevenson -

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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)

K173678

Device Name

Diode Laser Cap (Model: COSMO-030, COSMO-020, COSMO-010)

Indications for Use (Describe)

Diode Laser Cap is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V or females with androgenic alopecia who have Ludwig-Savin Classifications of I-II and both with Fitzpatrick Skin Phototypes I-IV.

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

"510(k) Summary" as required by 21 CFR Part 807.92.

Date: 2017.11.21

I. Submitter

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II. Device

Type of 510(k): Traditional

Common Name: Lamp, non-heating, for promotion of hair growth

Trade Name: Diode Laser Cap

Classification Name: Infrared lamp per 21 CFR 890.5500

Review Panel: General & Plastic Surgery

Regulatory Class: II

Product Code: OAP

Regulation Number: 21 CFR 890.5500

III. Predicate Device

1) Predicate device

<u>Applicant</u>	<u>Predicate Device</u>	<u>510(k) Number</u>	<u>Approval Date</u>
EGlobal, LLC	illumiflow Laser Cap	K162071	Feb.24, 2017
Capillus, LLC	Capillus laser domes	K163170	Jan.31, 2017

2) Reference device: None

IV. Device Description

The COSMO-030 and COSMO-010 Diode Laser Cap is a dome-shaped low level laser therapy (LLLT) device designed to promote hair growth in women and men by exposing the entire scalp to the photobiostimulation of 272 visible red light-emitting diodes at 650nm and 5mW each. The Cap is designed with an outer plastic cover and a protective inner liner (containing the electronics

and laser array) and is powered by an included battery pack. The COSMO-020 Diode Laser Cap is exactly the same as the COSMO-030 with the exception of the number of diodes which is respective of model (148 diodes in COSMO-020).

V. Indications for Use

Diode Laser Cap is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V or females with androgenic alopecia who have Ludwig-Savin Classifications of I-II and both with Fitzpatrick Skin Phototypes I-IV.

VI. Comparison of Technological Characteristics With the Predicate Device

The Diode Laser Cap is substantially equivalent to the predicated device based on intended use, design, specifications and performance.

The Diode Laser Cap raises no safety or efficacy concerns when compared to the predicate devices.

Information for predicate device was obtained from publicly available sources, including the 510(k) Summary and device instruction manual. A technical comparison to the predicate is provided below:

<u>Comparison Elements</u>	<u>Subject Device</u>	<u>Predicate Device 1</u>	<u>Predicate Device 2</u>
K Number	Pending	K162071	K161370
Trade name	Diode Laser Cap	illumiflow Laser Cap	Capillus laser domes
Classification name	Infrared Lamp	Infrared Lamp	Infrared Lamp
Product code	OAP	OAP	OAP
Intended use/Indications for Use	Diode Laser Cap is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa~V or females with androgenic alopecia who have Ludwig-Savin Classifications of I~II and both with Fitzpatrick Skin Phototypes I to IV.	The illumiflow Laser Cap is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa~V or females with androgenic alopecia who have Ludwig-Savin Classifications of I~II and both with Fitzpatrick Skin Phototypes I to IV	The Capillus laser domes 82, 202, 272 Pro, 272 OfficePro, 302, 312, and 352, are intended to treat Androgenetic Alopecia and promote hair growth in males who have Norwood – Hamilton Classifications of IIa to V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females

<u>Comparison Elements</u>	<u>Subject Device</u>	<u>Predicate Device 1</u>	<u>Predicate Device 2</u>
			who have Ludwig (Savin) Scale I-1 to I-4, II-1, II-2, or frontal; both with Fitzpatrick Skin Types I to IV.
Location for use	OTC application	OTC application	OTC application
Type of Light	Visible red light-emitting diodes	Visible red light-emitting diodes	Visible red light-emitting diodes
Wavelength	650nm	650nm	650nm
Amount of laser diodes	COSMO-010: 272 COSMO-020: 148 COSMO-030: 272	272	Capillus 82: 82 Capillus 202: 202 Capilus 272 Pro: 272
Energy of per laser diode	5mW	5mW	5mW
Classification according to IEC60825-1	Class 3R	Class 3R	Class 3R
Treatment time	Each treatment: 30min 16 weeks, every other day (indefinite)	Each treatment: 30min 16 weeks, every other day (indefinite)	Each treatment: 30min 17 weeks, every other day (indefinite)
Applicable people	Norwood-Hamilton IIa~V (males) Ludwig-Savin I~II (females)	Norwood-Hamilton IIa~V (males) Ludwig-Savin I~II (females)	Norwood-Hamilton IIa~V (males) Ludwig-Savin I~II or frontal (females)
Applicable skin	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV
Helmet/Cap design	Yes	Yes	Yes
Dimension	(L*W*H) COSMO-010: 23*18*9cm COSMO-020: 22*18*9cm COSMO-030:	Perimeter: 61cm Diameter: 19cm	Unknown

<u>Comparison Elements</u>	<u>Subject Device</u>	<u>Predicate Device 1</u>	<u>Predicate Device 2</u>
	22*18*9cm		
Weight	COSMO-010: 0.22kg COSMO-020: 0.26kg COSMO-030: 0.26kg	0.22kg	Unknown
Environment for operation	Temperature: 10 °C ~30°C (50°F~86°F) Humidity: 20%~80%	Temperature: -10 °C ~60°C (14°F~140°F) Humidity: 20%~80%	Temperature: 5 °C ~40°C (41°F~104°F) Humidity: 30%~80%
Environment for storage	Temperature: -10 °C ~60°C (14°F~140°F) Humidity: 20%~80%	Temperature: -10 °C ~60°C (14°F~140°F) Humidity: 20%~80%	Unknown
Safety feature	Complied with IEC60601-1, IEC60601-1-11, IEC60601-1-2 and IEC60825-1 Complied with IEC62133 (Battery pack) Complied with IEC60950 (Adapter)	Complied with IEC60601-1, IEC60601-1-2 and IEC60825-1 Complied with IEC62133 (Battery) Complied with IEC60950 (Charger)	Complied with IEC60825-1 Complied with IEC60950 (Charger)
Biocompatibility feature	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10.	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10.	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the Diode Laser Cap was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological

Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process, Document Issued on June 16, 2016", as recognized by FDA. The battery of testing was performed to, and passed, including:

- ISO 10993-5:2009/(R)2014, Biological Evaluation of Medical Devices –Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010, Biological Evaluation of Medical Devices –Part 10: Tests for Irritation and Skin Sensitization

2) Electrical and EMC Safety

Electrical safety and EMC safety testing was performed to, and passed, the following standards:

- IEC 60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Medical electrical equipment –Part 1-11: General requirements for basic safety and essential performance –Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-1-2 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility – Requirements and tests

In addition, testing to IEC 60825-1 certifies the laser system to classification 3R, which is the same as the predicate devices. And the charger conforms to IEC 60950 and the battery to IEC 62133.

Summary

Based on the above performance as documented in this application, Diode Laser Cap was found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, the Diode Laser Cap is to be concluded substantial equivalent to its predicate devices.