Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

FDA/CDRH/DCC
DEC 18 2015
RECEIVED

December 16, 2015

Food and Drug Administration
Center for Devices and Radiological Health Document Mail Center, W066-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

K153618

RE: **SPECIAL 510(k) Device Modification** Submission for the **Capillus202.**

The legally marketed device for which the design modification is applied is Capillus272 Pro; K143199.

To comply with the standards of the e-Copy program, "the eCopy is an exact duplicate of the paper copy".

Dear Sir or Madam:

Capillus, LLC via this submission is requesting market access in the U.S. for the Capillus202. The Capillus202 is the same cap in every way excepting the number of diodes, which is reduced to 202 diodes as opposed to 272 – this is the **only** change between models Capillus272 Pro and Capillus202. The contact person for this submission is Patricia Schnoor, Quality Manager for Capillus. She may be contacted at:

Capillus, LLC
1715 NW 82nd Avenue
Miami, FL 33126
T. 786-888-1874
F. 305-418-7581
Email. pschnoor@capillus.com

Exactly as the previous version, the Capillus202 is a Low-Level Laser Therapy (LLLT) device operating at 650 nanometers. It is rated as a Class 3R laser in accordance with IEC 60825 as recognized by the FDA.

Pursuant to Part 21 CFR 807.95, the FDA may disclose the existence of this premarket notification submission.

The Capillus272 Pro received clearance through K143199; Capillus LLC submits this design change for clearance based on the previous model. To support the acceptability of the change, the sponsor offers the flowing rationale: The Hairmax Lasercomb (HMLC) is the first device cleared in the OAP category and a reference device for the class. The HMLC had only 8 laser diodes in its first cleared device; since then, several other models, from HairMax and other manufacturers have cleared with diodes numbering from 8 to 272 (Capillus) and many quantities in between; as well as different external configurations, such as caps, combs, and panels. Some models have been cleared with a combination of lasers and LEDs. All of these devices have provided precedent for the reduction of the number of laser diodes

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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without sacrificing efficacy. Capillus LLC intends to offer a lower cost option to patients, recognizing that the efficacy is maintained at least at the level of other devices with fewer diodes, and is still at a level commensurate with expectations for the device category OAP. This request conforms to Part 21 CFR 890.5500.

The Capillus202 is classified as a class II medical device, for prescription use pursuant to Part 21 CFR 801 Subpart D. The appropriate panel is General & Plastic Surgery. The enclosed documentation is submitted in support of the request by the sponsor to receive marketing clearance forthe Capillus202 based upon limited device modification to the referenced device (Capillus272 Pro) pursuant to Part 21 CFR 807.92 (a)(3). 21 CFR 807.81(a)(3). The sponsor states the Capillus202 demonstrates an extremely low level of risk to subjects receiving the therapy and a commensurate level of therapeutic efficacy to the previous model.

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Therefore, the sponsor requests marketing clearance for the Capillus202, commensurate with the Capillus272 Pro, for the intended use of promoting hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications of I – II, and with Fitzpatrick Skin Phototypes I to IV.

Very truly yours,

Patricia Schnoor
Quality, Safety, & Compliance Manager
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Section 1

Capillus, LLC

510(k) Special Device Modification Submission for the CAPILLUS202

December 16, 2015

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

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Section 2

Medical device User Fee Cover Sheet

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
CAPILLUS LLC 1715 NW 82nd Ave Miami FL 33126 US	Patricia Schnoor 2.1 E-MAIL ADDRESS pschnoor@capillus.com 2.2 TELEPHONE NUMBER (include Area code) 786-888-1874
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)	2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:

[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center

[X] CDRH
[ ] CBER

3.2 Select one of the types below

[X] Original Application

Supplement Types:

[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD168324

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

$(b)(4) 16-Dec-2015

Form FDA 3601 (05/13)

"Close Window" Print Cover sheet

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: FDA User Fees
Pay.gov Tracking ID: (b)(4)
Agency Tracking ID: (b)(4)
Transaction Date and Time: 12/16/2015 20:19 EST

Payment Summary

Address Information

Account Holder Name: CAPILLUS LLC
Billing Address: 1715 NW 82nd Ave
Billing Address 2:
City: Miami
State / Province: FL
Zip / Postal Code: 33126
Country: USA

Account Information

Card Type: American Express
Card Number: ********** (b)(4)

Payment Information

Payment Amount: (b)(4)
Transaction Date and Time: 12/16/2015 20:19 EST

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Section 3

CDRH Premarket Review Submission Cover Sheet (Form 3514)

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☒ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: CAPILLUS LLC	Establishment Registration Number *(if known)*: 3010123655		
Division Name *(if applicable)*	Phone Number *(including area code)*: 786-888-1874		
Street Address: 1715 NW 82nd AVE	FAX Number *(including area code)*: 305-418-7581		
City: MIAMI	State / Province: FLORIDA	ZIP/Postal Code: 33126	Country: USA
Contact Name: PATRICIA SCHNOOR			
Contact Title: MANAGER, QUALITY & REGULATORY AFFAIRS	Contact E-mail Address: pschnoor@capillus.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

PSC Publishing Services (301) 443-6740 EF

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] New Device
- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Packaging
  - [ ] Sterilization
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Response to FDA correspondence:

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [ ] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [x] Other Reason *(specify)*:

New configuration of finished product - reduced to 202 (from 272) laser diodes.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	OAP	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- ☐ 510 (k) summary attached
- ☒ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	143199	1	Capillus 272 Pro	1	Capillus, LLC
2	150613	2	LaserCap LCPro	2	Transdermal Cap Inc.
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Laser comb, Hair growth laser, OAP

	Trade or Proprietary or Model Name for This Device		Model Number
1	Capillus202	1	Capillus202
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K143199	2 K151516	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: OAP

C.F.R. Section *(if applicable)*: 21 CFR 890-5500

Device Class: ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel: General and Plastic Surgery

Indications *(from labeling)*

Treat hair loss and promote hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications of I-II, and with Fitzpatrick Skin Phototypes I-IV.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name: Capillus, LLC		Establishment Registration Number: 3010123655	
Division Name *(if applicable)*		Phone Number *(including area code)*: 786-888-1874	
Street Address: 1715 NW 82nd Ave		FAX Number *(including area code)*: 305-418-7581	
City: Miami		State / Province: Florida	ZIP Code: 33126 / Country: USA
Contact Name: Patricia Schnoor	Contact Title: Manager, Quality & Regulatory Affairs	Contact E-mail Address: pschnoor@capillus.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
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City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

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SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

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 control number.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Section 4

SPECIAL 510(k) Cover Letter

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

December 16, 2015

Food and Drug Administration
Center for Devices and Radiological Health Document Mail Center, W066-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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Capillus, LLC
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Miami, FL 33126
T. 786-888-1874
F. 305-418-7581
Email. pschnoor@capillus.com

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Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

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Very truly yours,

Patricia Schnoor
Quality, Safety, & Compliance Manager
Capillus LLC
1715 NW 82nd Avenue
Miami, FL 33126
T. 786-888-1874
M: 305-255-3208
F. 305-418-7581
Email. pschnoor@capillus.com
www.capillus.com

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Section 5

Indications for Use

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

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)*

Device Name
Capillus202

Indications for Use *(Describe)*
The Capillus202 is indicated to treat hair loss and promote hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications of I-II, and 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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Section 6

Special 510(k) Summary

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Special 510(k) Summary

Capillus, LLC

Date Prepared: **December 16, 2015**

Submitter's Contact Information:

Name: Patricia Schnoor

Address: Capillus LLC
1715 NW 202nd Avenue
Miami, FL 33126

Estab't Reg# 3010123655

Telephone: (786) 888-1874
Facsimile: (305) 418-7581

Name of Device and Name / Address of Sponsor:

Trade Name: Capillus202

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

Classification Name: Infrared lamp per 21 CFR 890.5500

Classification Code: OAP (Laser, Comb, Hair)

Sponsor Contact Information: Patricia Schnoor
Capillus LLC
1715 NW 82nd Avenue
Miami, FL 33126

Telephone: (786) 888-1874

Predicate Devices:

Device Trade Name	Manufacturer	510(k)
Capillus272 Pro	Capillus LLC	143199
LaserCap LCPro	Transdermal Cap, Inc	150613

Reference Devices:

Device Trade Name	Manufacturer
Hairmax Lasercomb	Lexington International

Intended Use / Indications for Use:

The Capillus202 is indicated to treat hair loss and promote hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications of I-II, and with Fitzpatrick Skin Phototypes I-IV.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Technological Characteristics

The Capillus202 is exactly the same as the Capillus272 Pro in every way **except** the following:

1. **The Capillus202 has fewer diodes – 202 compared to 272 for Capillus272 Pro**

The Capillus272 Pro consists of 272 red, visible light, diode lasers operating at 650 nanometers, configured within an outer helmet and protective inner liner, and configured for portable use with rechargeable battery and adapter. The Capillus202 consists of 202 red, visible light, diode lasers operating at 650 nanometers, configured within an outer helmet and protective inner liner, and configured for portable use with rechargeable battery and adapter.

Just as for the previous version, the helmet system will automatically pause therapy if the subject's head is moved outside of the zone of radiation and will resume therapy when the correct head position is re-established. This is achieved by a safety interlock. At the beginning and end of a therapy session, audible tones are delivered to the user, indicating that therapy has begun (2 beeps) or ended (one long beep). The system is powered by rechargeable Nickel Metal Hydride battery cells assembled into a proprietary battery pack. Both the battery pack and charger are fully compliant to recognized, international standards.

Design Control Activities:

The Capillus design and development team followed ANSI/AAMI/ISO 14971:2007/(R)2010 Risk Management: Medical devices – Application of risk management to medical devices. Significant changes included assessing the effect a reduction of lasers would have on the end product, both for safety and for efficacy. All residual risks are found acceptable and the risk management file and summary are available for review. Based on the Capillus272 Pro, the verification and validation activities remain the same (e.g. output of each laser, operation of safety interface, and output of power pack), and were performed and assessed by designated personnel qualified to perform such activities. All methods, tests, and acceptance criteria are stipulated on the verification and validation reports. All documents are available for review.

Safety ratings remained the same; there was no change to the output of the individual lasers ($\leq$ 5mW); however, the "dose" (total delivered energy/cm2) is reduced due to reduced number of lasers. This may affect efficacy; this observation is made based on the performance of other devices similar to Capillus that are currently cleared under device code OAP and utilize much fewer than 272 lasers (The closest equivalent in light sources is Transdermal with a total of 224 lasers).

Use instructions do not change. Indications for use and the dose schedule remain exactly the same as for Capillus272 Pro and as for other devices in the same category (product code OAP); which is for maximum 30 minutes, every other day.

The output of the laser diodes was verified to remain the same (each diode) as for the previous model. Design control activities were followed per 21 CFR 820.30:

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a) **General: The Capillus LLC Quality Management System is compliant to the requirement of the quality system regulation and specifically to design controls as stipulated by 21 CFR 820.30.**

b) **Design and development planning:** During project planning activities, the risks were identified and assessed with respect to the proposed design change. The proposed design change was minimal and affected only the number of diodes in the PCB array. The power pack remains exactly the same. Review of the risk assessment from previous model revealed no significant changes or risks are identified for the new model Capillus202. Vigilance activities for the Capillus272 Pro indicated that there were no significant problems identified (no adverse events reported).

c) **Design input:** Design requirements for the Capillus272 Pro are transferred to the Capillus202 and an input/output matrix completed as for the original project.

d) **Design output:** Design requirements for the Capillus272 Pro are transferred to the Capillus202 and an input/output matrix completed as for the original project. Design outputs are verified per performance tests.

e) **Design review:** Appropriate design reviews were conducted; in this case (due to minimal change), a technical evaluation, and a verification of inputs and outputs (physical values) were completed.

f) **Design verification:** All verification activities to assess the impact of the change (reduction of number of laser diodes) were completed. Laser diode output remains the same, but total dosage is reduced. Since the cap is intended to be used indefinitely (if treatment is stopped, results are lost – see instructions for use), this will likely affect only the time required to witness the same result as achieved with the Capillus272 Pro. The Capillus202 is offered as a lower-cost alternative.

g) **Design validation:** Feedback from hair restoration specialists and consumers indicate that a lower-cost alternative is desired. The slower efficacy is accepted, with the understanding that treatment is intended to be indefinite.

h) **Design transfer:** The Capillus family of products are manufactured on-site in the factory in Miami. Design transfer was minimal; training requirement to the new PCB was minimal, and all other components (including overall build) remained the same.

i) **Design changes:** The design of all models follows our established design control, change control, document control procedures.

j) **Design history:** The design history file for the Capillus202 is available for review.

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Performance Data:

All verification and validation activities were performed by designated individuals. The results (available for review) demonstrate that the predetermined acceptance criteria were met.

Performance testing was conducted to confirm compliance to design specifications; all functions have been verified to operate as designed. All acceptance criteria were met by the device.

The Capillus202 conforms to the standard IEC-602025-2007-03; This IEC standard is a recognized and accepted standard by the FDA. The guidance document for this accepted standard is found in the Federal register, July 26, 2001 (volume 66, Number 144) [page 39049 39050]. This report validates for the Capillus202 the laser class of 3R which establishes the AEL (accessible emission limits) as 5 milliWatts maximum. The charger conforms to IEC 61959.

The performance data available for review demonstrates that the Capillus202 has exactly the same laser wavelength, output power (per diode), output beam, energy type, laser field, and treatment area as the original Capillus272 Pro cleared under K143199. Total "dose" – delivered energy over time - (J/cm^2) is logically reduced. Just as for Capillus272 Pro (K143199) and reference devices, there are no reported adverse events for this technology.

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Substantial Equivalence

The Capillus202 is the same technology used by Capillus272 Pro (K143199) and other reference devices; specifically, Transdermal Cap (K150613). The Capillus202 is as safe and (commensurate to number of diodes) effective as the Capillus272 Pro, as well as other reference devices in its class, such as the Hairmax Lasercomb.

Capillus272 Pro	Capillus202	LaserCap LCPro
K143199	Candidate	K150613
LLLT Device Type	LLLT Device Type	LLLT Device Type
Prescription Use	Prescription Use	Prescription Application
Intended Use - Androgenic Alopecia	Intended Use - Androgenic Alopecia	Intended Use -Androgenic Alopecia
Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class 3R
Helmet/Cap Design	Helmet/Cap Design	Helmet/Cap Design
650nm	650nm	650nm
Marketing clearance for Females	Marketing clearance for Females	Marketing clearance for both genders
Passive Use-Hands Free	Passive Use-Hands Free	Passive Use-Hands-Free
272 Laser Diodes	202 Laser Diodes	224 Laser Diodes
OAP Classification	OAP Classification	OAP Classification
Classification Name -Infrared Lamp	Classification Name -Infrared Lamp	Classification Name - Infrared Lamp
Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non- Heating
General & Plastic Surgery Committee	General & Plastic Surgery Committee	General & Plastic Surgery Committee
Fitzpatrick Skin Phototypes - I- IV	Fitzpatrick Skin Phototypes - I- IV	Fitzpatrick Skin Phototypes - I -IV
Ludwig-Savin I-II (females)	Ludwig-Savin I-II (females)	Ludwig-Savin I-II (females)
Efficacy Rates - High Compared to Placebo	Efficacy Rates - High Compared to Placebo	NA
Treatment- 17weeks, every other day (indefinite)	Treatment- 17weeks, every other day (indefinite)	Treatment - 16 weeks, every otherday (indefinite)
Device Class II	Device Class II	Device Class II

Capillus LLC believes that with the exception of the configuration of the optical elements, the Capillus202 is the same device in form, function, safety, and efficacy as the previous version and the predicate device(s). The Hairmax Lasercomb, offered as a reference, is proof of the functionality and acceptability of devices with fewer laser diodes cleared by the FDA in the category of OAP, both technically and clinically. Capillus LLC believes that the difference in the physical appearance, number of diodes, or in the method of delivering the radiant energy of the systems is of no consequence and does not affect the therapeutic value or the safety profile.

All compliant LLLT systems which use red light diode lasers are classified as class 3R laser systems by the IEC standard for allowable emission levels, which is a recognized standard by the FDA as well, and the adverse event profile is the same.

For these reasons, the Capillus202 satisfies the FDA's requirements (for device modification notification) with respect to intended use, and technological and design characteristics. Additionally, no new safety or efficacy concerns are

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raised due to the minor difference present between devices.

Signed:

Patricia Schnoor

Quality, Safety & Compliance Manager

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 7

Truthful and Accurate Statement

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Premarket Notification: Truthful and Accurate Statement

I certify that, in my capacity as the Quality Manager of Capillus, LLC, I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material has been omitted.

Signature, Patricia Schnoor

December 16, 2015
Date

Premarket Notification [510(k)] Number

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 8

Financial Certification

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Financial Certification

No clinical studies/trial were conducted in behalf of this application; therefore this section is not applicable.

Signature, Patricia Schnoor

December 16, 2015
Date

Premarket Notification [510(k)] Number

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 9

Executive Summary

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXECUTIVE SUMMARY

The Capillus202

Exactly as the previous model referenced in this submission, the Capillus202 is a Low-Level Laser / Light Therapy (LLLT) device operating at the 650-nanometer (nm) wavelength of visible light. A low-level laser/light therapy device is one in which exposure to the laser/light radiation will not cause the human body temperature to sustain any rise in temperature above the base normal of 37.0 degrees centigrade. The two models are exactly the same with regard to all parameters except the number of diodes included.

The laser system is classified as 3R according to IEC 60825. The system is configured as a low-profile helmet or baseball style cap. Within the helmet are contained 202, 5 milliWatt (mW) laser diodes, affixed in an evenly distributed pattern on a PCB protected underneath a clear inner liner. The laser/light emission levels cannot be adjusted by the user/operator. Delivered energy is fixed by the characteristics of the diode.

A standard therapy session is 30 minutes, depending on the prescribing physician. The Capillus202 contains an analog optical power output monitor that controls laser system emission levels not to exceed 5 milliWatts. Any emission levels that deviate from the allowable maximum for a class 3R laser will cause the system to shut down. A photodiode sensor is located within the pathway to the human head to control all emissions. The laser/light will not emit radiation unless the head is properly positioned within the helmet and will cause the therapy to PAUSE, if moved out of proper position, until the head is re-positioned correctly. This feature prevents therapy sessions from being performed in an inadequate manner and prohibits use if the helmet is not properly positioned on the head.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Model Comparison

The Capillus272 Pro (cleared under K143199) and the Capillus202 are identical in every way except the number of diodes included. As such, the devices share the same clinical efficacy and safety profiles. For purposes of comparative analysis, the following side-by-side comparison is presented.

Capillus272 Pro	Capillus202
272, 5mW laser diodes	202, 5mW laser diodes
Automated, precise pattern of delivery	Automated, precise pattern of delivery
Algorithm controlled and non-variable	Algorithm controlled and non-variable
650nm visible light	650nm vis ble light
Class 3R laser	Class 3R laser
LLLT	LLLT
"Hat" worn on head, portable	"Hat" worn on head, portable

Performance Testing:

Laboratory tests were performed pursuant to IEC -60825-1 Edition 1.2 2001-08 for a class 3R laser; EN60335-1:2002 + A1:2004 + A2:2006; EN60335-2-23:2003 5.0 Ed+ Corr. 2:2008 + A1:2008; EN62233: 2008; EN55014-1: 2006+ A1:2009 +A2:2011 EN55014-2:1997+A1:2001+ A2:2008; EN61000-3-2: 2006; EN61000-3-3: 2008; and EN602025-1:2007-03. The Declaration of Conformity is available in the Performance Testing, EMC, and Electrical Safety section.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 10

Device Description

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEVICE DESCRIPTION

The Capillus202 is a low-level laser/light system operating at 650 nanometers. The physical configuration is that of a helmet or baseball cap containing an inner and outer shell. The system operates from a battery pack, which is charged by an adapter. This configuration permits mobility during therapy sessions. The adapter operates on line voltages from 110 to 260 volts; the device will not operate while charging. The helmet's inner liner permits full adjustment to any head shape by means of semi-rigid, conforming materials. The helmet contains 202, 5 milliWatt laser diodes that emit red (visible) light. This system delivers fixed laser emission levels as defined by the diode characteristics, which cannot be altered by the operator.

The device helmet is constructed of a biocompatible class of plastic – exactly the same material as is used for the Capillus272 Pro. The Capillus202 is a hands-free system, requiring no active processes by the user, other than starting a therapy session. The laser light reaches the human scalp, emitted directly from behind the clear inner liner, without any focusing lens system. The device helmet covers the upper one-third of the head, with orientation from the bridge of the nose in the anterior, toward the occipital notch in the posterior and from the upper most portion of the ear on both sides of the head. When operated correctly, the helmet remains approximately 1-2 centimeters (depending on head shape/size) from the scalp.

There is no maintenance for the operator to perform other than maintaining a clean inner liner and external surfaces. Simple disinfectant wipes that are commercially available are adequate for cleaning the plastic liner should it become covered with scalp oils or hair lotion. There are no accessories for this system, no safety devices (e.g. laser safety glasses) required by regulation or international standard, no biocompatible hazards or concerns, and no consumable products.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 11

Substantial Equivalence Discussion

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SUBSTANTIAL EQUIVALENCE DISCUSSION

Capillus LLC declares the candidate model, Capillus202, to be exactly the same as the previous, cleared model, Capillus272 Pro, with only 1 exception:

1. The Capillus202 has fewer diodes than its predecessor (202 diodes compared to 272 in the predecessor).

Functionally, there is no question that the intended use, regimen, and technology are the same for both devices. Both contain class 3R laser diodes and employ the same user regimen and indications for use. The delivery of total energy (from the Capillus202) to the target tissue, i.e., the human scalp, is reduced (for the same treatment period) because the number of diodes are fewer than the predecessor.

At this time, there is no published empiric evidence that establishes the ideal source of light, pattern of delivery of the light or scalp coverage (number and placement of diodes). An optical designer may in fact provide a scientific basis for adopting any of the variables in a specific format, as is the case between the two referenced models. Capillus' optical designer postulates that more light elements may lead to increased efficacy due to coverage (little to no gaps in light coverage); however, a unit with fewer diodes will still offer appropriate efficacy to a user at a lower cost.

If therapy outcome of the two referenced models is similar and the physical design, wavelength choice, and treatment session time are exactly the same, then the design modification of fewer diodes is not significant. In this case, the only difference between the Capillus202 and the Capillus272 Pro is the number of light elements, which presents no new safety or efficacy concerns.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The Capillus272 Pro and the Capillus202 possess only one difference which Capillus believes to be insignificant and should not prevent the FDA from coming to the same conclusion, which is that the burden of demonstrating substantial equivalence is overwhelming in favor of acceptance. The comparison follows:

Capillus272 Pro	Capillus202
K143199	
LLLT Device Type	LLLT Device Type
Prescription Use	Prescription Use
Intended Use - Androgenic Alopecia	Intended Use - Androgenic Alopecia
Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class 3R
Helmet/Cap Design	Helmet/Cap Design
650nm	650nm
Marketing clearance for Females	Marketing clearance for females (proposed)
Passive Use-Hands Free	Passive Use-Hands Free
272 Laser Diodes	202 Laser Diodes
OAP Classification	OAP Classification
Classification Name -Infrared Lamp	Classification Name -Infrared Lamp
Common Usage Name - Lamp, Non-Heating Heating	Common Usage Name - Lamp, Non-Heating Heating
General & Plastic Surgery Committee	General & Plastic Surgery Committee
Fitzpatrick Skin Phototypes - I- IV	Fitzpatrick Skin Phototypes - I- IV
Ludwig-Savin I-II (females)	Ludwig-Savin I-II (females)
Efficacy Rates - High Compared to Placebo	Efficacy Rates – within 35 to 45% range
Treatment- 17weeks, every other day	Treatment- 17weeks, every other day
Device Class II	Device Class II

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The safety risk assessment for this class of laser/light product is considered non-significant risk. No new safety concerns were identified in evaluation according to IEC 14971. The Capillus202 does not present any known or new risks to the user.

Conclusion:

Technologically and clinically, the Capillus202 represents a minor modification from the cleared Capillus272 Pro; no new risks or efficacy issues have been identified.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 12

Proposed Labeling

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PROPOSED LABELING

All product labels are affixed to the outside, rear position of the Capillus202 Cap.

Copy of the rating plate
Identification and date marking

Model: Capillus202
Serial: CX272 1502 00001
Mfg by: Capillus, LLC
Coral Gables, FL 33146
Toll-Free USA: 1 (888) 272-9599

Serial number taxonomy: CX272 = model; 1502=YYMM; 00001=number sequence of fabrication

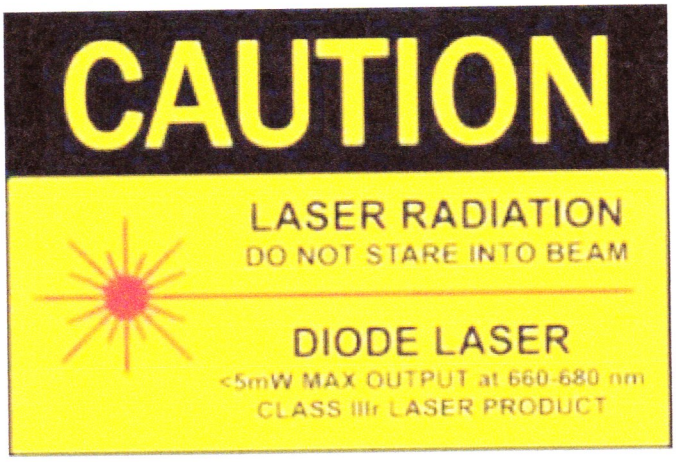
650 nm Class 3R Laser

The only change to the labeling is to replace "272" with "202" to indicate the number of diodes

All other elements REMAIN THE SAME

This is also true for the following use instructions (next pages). Instructions remain EXACTLY THE SAME except to replace "272" with "202"

Certification and caution label (Class 3R, pursuant to 21 CFR 1040.20)



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CAPILLUS202 USER INSTRUCTION MANUAL

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- Physical Parameters

CORPORATE INFORMATION

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IMPORTANT INFORMATION

Please read all instructions before using your Capillus202. Please keep these instructions for future reference and be sure to follow all warning and safety information included herein. If you have any questions regarding operation, please contact Capillus Customer Service toll-free at 1 (888) 82-9599 or via email at support@capillus.com.

All product information and articles are intended to be for informational purposes only.

ABOUT THE CAPILLUS202

The Capillus202 is a portable home-use laser device available by prescription through licensed physicians only. The Capillus202 features a laser dome embedded with 202 laser diodes on its interior surface, and is powered by a certified rechargeable battery pack that connects to the dome. The laser dome is worn under a sports cap included with the device. The battery pack can be slipped into the provided battery case which clips onto your waistband or belt. The Capillus202 provides low-level laser therapy to the scalp and hair follicles to stimulate cellular activity and promote the flow of blood. There is no need for constant user effort. The hands-free design makes it easy and comfortable to use while performing everyday activities.

INDICATIONS FOR USE

The Capillus202, is indicated to promote hair growth in females with Ludwig-Savin I-II Classifications of Hair Loss, with Fitzpatrick Skin Phototypes I - IV.

INTENDED USAGE

- The Capillus202 should be used only for the purpose described in this manual.
- The Capillus202 is intended for use on the human scalp only. Any other use is not recommended.

FREQUENCY OF USE

The Capillus202 should be used every other day (do not use for one full day between sessions). It is not recommended for use on consecutive days. Typically, the total time of each session is 30 minutes; however, your physician may prescribe a different treatment time. Exceeding the recommended times or frequency will not increase the effect of the Capillus202, and may in fact cause a negative effect. Do not exceed recommended usage.

DURATION OF USE

Although you should see significant results within 4 months The Capillus202 may be used indefinitely according to the instructions above. Cessation of use may result in a loss of new hair growth.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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WHAT'S INCLUDED

INSTRUCTIONS FOR USE

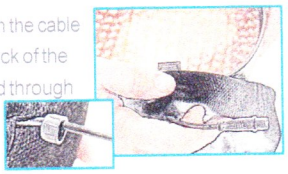
The Capillus202 should be used every other day (at least one day between sessions). It is not recommended for use on consecutive days. Typically, the total time of each session is 30 minutes; however, your physician may prescribe a different treatment time. Exceeding the recommended times or frequency will not increase the effect of the Capillus202. Do not exceed recommended usage. The references (A-H) in this section refer to the part list shown above in Diagram 1.

STEP 1

Unpack the components of the Capillus202 and make sure all the parts are present according to Diagram 1. All parts are stored in the Carrying Case (G) with exception of this User Manual (E). Battery Pack (B), Battery Case (C), Wall Charger (D) are packed within Drawstring Pouch (H) inside the Carrying Case. If there are parts missing contact customer service at 1-888-82-9599 or support@capillus.com.

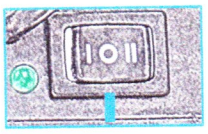
STEP 2

Place the Laser Dome (A) inside the Sports Cap (F) with the cable from the Laser Dome pulled through the slit on the back of the Sports Cap. Ensure that the black plastic lock is pulled through the slit, as well, for optimal comfort during use.



STEP3

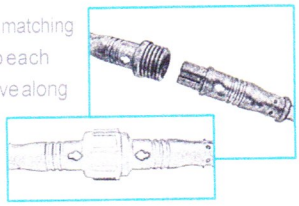
The Battery Pack (B) is packed ready for use inside the Battery Case (C). Make sure that the Battery Pack (B) switch is turned to the "Off" Position" indicated by the circle O.



Off Position O

STEP4

Connect the Laser Dome (A) to the Battery Pack (B) by matching up the small white indicator arrows on the cables to each component. Note that there are small pins and a groove along the edge that help match the cables properly. Important: The arrows must be aligned for the cables to make a proper connection. Once the arrows are aligned, push cables together and secure with the twist lock connector.



Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

STEP 5

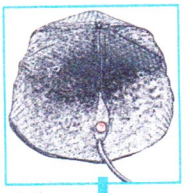
Place Laser Dome (A) with Sports Cap (F) on head and attach the Battery Case (C) holding the Battery Pack (B) to your belt or pant waist.

STEP 6

Once Laser Dome is on the head, switch position on Battery Pack (B) to "On", indicated by the single line I, for use. Indicator Light on Battery Pack should blink green. *Please note that there is a photo-diode sensor on each side of the device that only allows radiation to be emitted when the cap is on the head.*

On Position I

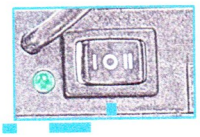
You will hear an audible tone when treatment begins and the emission indicator light on the back of the cap will light up (blink). Wear for treatment session of 30 minutes. (The Capillus82 should be used every other day.) Once the treatment period is over, the device will automatically shut off, you will hear an audible tone, and the emission indicator light will stop blinking.



Emission Indicator

STEP 7

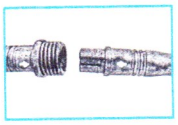
At the end of the treatment session, turn switch on Battery Pack (B) position to "Off" position and then remove the Laser Dome (A) from the head.



Off Position O

STEP 8

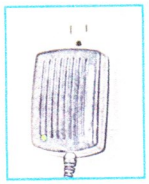
Disconnect the cable from the Laser Dome (A) from the cable to the Battery Pack (B).



INSTRUCTIONS FOR CHARGING BATTERY PACK

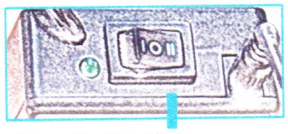
STEP 1

After several uses, you will need to recharge the Battery Pack as follows. Plug Wall Charger (D) into a power outlet. The indicator light on the Wall Charger (D) will be Green until you connect the Battery Pack needing a recharge.



STEP 2

Connect the Wall Charger (D) to the Battery Pack (B). Turn switch on Battery Pack (B) to "Charge" position, indicated by the "0". Please note that the indicator light on the Battery Pack does not turn on while charging.

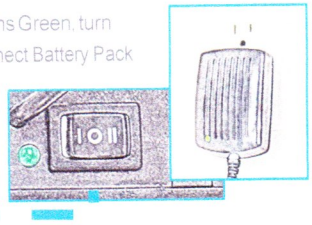


Charge Position II

Indicator light on Wall Charger (D) should turn from Green to Red when Battery Pack does not have a full charge. Leave Battery Pack (B) charging for 3-4 hours until indicator light on Wall Charger changes to Green.

STEP 3

When the indicator light on the Wall Charger (D) turns Green, turn switch on Battery Pack (B) to Off Position and disconnect Battery Pack from Wall Charger. Disconnect Wall Charger from power outlet and store parts in Carrying Case (G) until ready the next treatment session.



Off Position O

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

SAFETY LABELS

The following laser safety label (i) can be found on the cable of the Laser Dome (A).

ii can be found on the exterior of the Laser Dome (A).

(i)

(ii)

Model: Capillus202
Serial:
Mfg by: Capillus, LLC
Miami, FL 33126
Toll-Free USA: 1 (888) 272-9599

650 nm Class 3R Laser

Label symbols from bottom left to right (label (ii)): the first symbol indicates the device should not be disposed of in the normal waste stream; it should be taken to a recycling center for proper disposal. The second symbol indicates laser light radiation as described on label (i). The third symbol indicates Type BF applied part (60601-1); B=Body. F=Floating applied part. No conductive contact to patient.

The Capillus202 gives off no heat or harmful radiation, causes no pain and does not require the use of drugs or topicals.

EYE SAFETY CAUTION: Class 3R 5 MilliWatts, 650 Nanometers Red Laser Diodes.
DO NOT STARE DIRECTLY INTO THE LASER LIGHT.

WARNINGS & PRECAUTIONS

- ***Do not stare directly at laser light or its reflection. Prolonged eye exposure can cause eye damage.*** Using a mirror or lens to direct the laser to the eye will increase the danger.
- Do not point or shine the lasers at others, pets, etc.
- This Capillus202 unit is not a toy, nor is it intended for use by or on Children. The Capillus202 should be kept out of the reach of Children.
- Do not scratch, mark or otherwise damage the interior surface of the laser dome.
- Keep the Capillus202 away from children and pets.
- Do not expose the Capillus202 laser diodes to static or other high voltage. These lasers are Electrostatic Discharge sensitive.
- Do not adjust or modify the Capillus202. Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
- Never operate the Capillus202 if it has a damaged cord or plug. If it is not working properly or it has been dropped or damaged or submerged in water, return the product to Capillus, LLC for repair or replacement.
- Do not use the Capillus202 while the Battery Pack is connected to the Wall Charger.
- Do not put undue tension on the cords when untangling or straightening
- Do not use any power adapters or other sources of power, other than that provided with the Capillus202. Use only the power supply provided with the Capillus202.
- Do not store the unit near strong chemicals such as acids or bases.
- Do not place or store the unit where it can fall or be pulled into a tub or sink.
- Avoid getting the Capillus202 wet. This may result in electric shock.
- If the unit accidentally falls into water or other liquid, unplug it from the electrical outlet immediately. DO NOT REACH INTO OR TOUCH THE WATER.
- Only use the Capillus82 according to the instructions provided. Any other use may result in injury.
- Always connect the plug into outlet first, then attach the power supply to the unit.
- Always unplug the power adapter from the power outlet immediately following charge.

Do not disassemble any part of the Capillus202 and don't attempt to repair Capillus202 by yourself. Disassembling Capillus202 may damage it or may cause injury to you. If the Capillus202 is damaged, malfunctions, or comes in contact with liquid, contact Capillus. The lithium-ion battery in Capillus202 should be replaced only by Capillus.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

CONTRAINDICATIONS

- Laser therapy should not be used in conjunction with medications or products that are photosensitizing.
- Do not use the Capillus202 if you have cancer of the scalp.
- Do not use the Capillus202 if you are sensitive to pulsed light.
- Do not use the Capillus202 if you are sensitive to light of 650 nm in wavelength.
- Do not use if your physician has not prescribed you as a candidate for the Capillus202.
- Do not use the Capillus202 if you did not purchase the device on the advice of a doctor after completing a physical examination.
- This Capillus202 unit is not a toy, nor is it intended for use by or on Children. The Capillus202 should be kept out of the reach of Children.

MAINTENANCE INSTRUCTIONS

If it is necessary to clean the Capillus202 surfaces, please follow these instructions. Note: the Capillus202 has no parts that can be serviced by the user. If service is required, contact Capillus, LLC.

- DISCONNECT ALL CABLES ON THE CAPILLUS202 BEFORE CLEANING
- To clean the Capillus202, gently wipe the inner surface of the laser dome (A) with an alcohol wipe or a water moistened cloth. Do not use excessive pressure or force as this may damage the Capillus202 unit.
- DO NOT use Acetone or any other solvents on any part of the Capillus202. Acetone and other solvents will damage the unit and void the warranty.
- Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in direct radiation exposure.

OPERATING & STORAGE INFORMATION

- Operating Temperature: The Capillus202 is designed to work in ambient temperature between 50° and 86° F (10° and 30° C) and shipped or stored in temperatures between 41° and 104° F (5° and 40° C). The Capillus202 can be damaged and battery life shortened if stored or operated outside of these temperature ranges.

WARRANTY

We provide a 1 year limited warranty. Capillus warrants the Capillus202 against defects in materials or workmanship for a period of 1 year from the date of purchase from a Capillus authorized physician. To activate your warranty on the Capillus202, register your device within 30 days of purchase at www.capillus.com/activatewarranty. If a defect in material or workmanship exists, Capillus will repair or replace the necessary parts with new or refurbished parts at no charge. Any replacement part will be covered under the original 1 year limited warranty. This Warranty does not cover damages caused by acts of God, misuse, negligence, accident, or modification of any part of the unit as determined by our return department. This Warranty does not cover damage due to improper operation or maintenance, connection to improper voltage supply, or attempted repair by anyone other than the company. Failure to use and maintain the Capillus202 in accordance with the instructions in this manual will void the product warranty.

TROUBLESHOOTING

For any problems operating the Capillus202, please contact Capillus Customer Service at 1-888-82-9599 or support@capillus.com. If you experience any discomfort during or after use, please discontinue use immediately and contact your physician.

NOTICE: Do not attempt to repair any portion of the Capillus202. If a malfunction occurs, disconnect the Capillus202 from the electrical source and contact Capillus, LLC Customer Service toll-free at 1-888-82-9599 or email at support@capillus.com.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

CAPILLUS82 SPECIFICATIONS

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

LASER

- Type: 5 milliWatt semiconductor, gallium arsenide
- Wavelength: 650 nanometers +/- 5
- Radiant Power Emission: 1010 milliWatts
- Output Mode: Pulsed
- Pulse Width: 50 milliseconds
- Pulse Interval: 150 milliseconds
- Pulse Rate: 6.9444 Hertz +/- 1 Hertz

BATTERY PACK

- Battery Group: Nominal Voltage 11.1 Volts (12.6 Volts when Fully Charged)
  Capacity 2200 mAh
  3 (3.7 Volt Certified Lithium-Ion Batteries)

WALL CHARGER

- Power Input: Alternating Current 100-240 Volt, 50/60 Hertz
- Power Output: +12.6 Volt, 1 A

The power supply for the Capillus202 has been designed for use in the United States and Internationally. The power supply will adapt to 110 Volt/60 cycles (US) or 240 volt/50 cycles. If the power outlets in your country use plugs different than the type supplied with the Capillus202, it will be necessary to obtain an appropriate country specific plug adapter (these are not supplied with this unit).

AMBIENT OPERATING CONDITIONS

- Temperature: 10°Celcius (50°Fahrenheit) ~ 30°Celcius (86°Fahrenheit)
- Humidity: 30% ~80%
- Atmospheric Pressure: 700 Pascals ~ 1060 Pascals

CLASSIFICATIONS

FDA Classification: Class II Medical Device

CDRH Classification: Class 3R Laser Product

EYE SAFETY

Nominal Ocular Hazard Distance: 23 centimeters at 650 nanometers

Unless wearing suitable Laser Safety Eye-wear Protection, do not stare at the laser light as it can damage your eyes.

REGULATORY COMPLIANCE

Capillus, LLC lasers comply with 21 CFR 1040 for Class 3R Laser Products as administered by the Center for Device and Radiological Health of the US Food and Drug Administration and standards IEC60601 and IEC60825 of the International Electrotechnical Commission.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

PHYSICAL PARAMETERS

- Laser Dome: *Weight:* 6.4 ounces (180 grams)
  Dimensions: 8 3/8 inches (21.27 centimeters) Deep
  7 1/2 inches (19.05 centimeters) Wide
  3 3/4 inches (9.53 centimeters) High
- Battery Pack: *Weight:* 8 ounces (228 grams)
  Dimensions: 1 1/8 inches (2.86 centimeters) Deep
  2.5 inches (6.35 centimeters) Wide
  4 inches (10.16 centimeters) High
- Wall Charger: *Weight:* 3.5 ounces (180 grams)
  Dimensions: 1.25 inches (3.2 centimeters) Deep
  1.75 inches (4.45 centimeters) Wide
  2 3/4 inches (6.99 centimeters) High
- Sports Cap: *Weight:* 2.4 ounces (68 grams)
- Carrying Case with Strap: *Weight:* 12.8 ounces (364 grams)
  Dimensions: 13 inches (33.02 centimeters) Deep
  10.5 inches (26.67 centimeters) Wide
  5 inches (12.7 centimeters) High
- Battery Case: *Weight:* 1.2 ounces (34 grams).
  Dimensions: 1 1/4 inches (3.18 centimeters) Deep
  2 7/8 inches (7.3 centimeters) Wide
  4 1/4 inches (10.8 centimeters) High
- Drawstring Pouch: *Weight:* 0.8 ounces (22 grams)
  Dimensions: 8 3/4 inches (22.23 centimeters) High
  6 inches (15.24 centimeters) Wide
- User Manual: Weight: 0.3 ounces (8 grams)
  Dimensions: 4 1/4 inches (10.8 centimeters) Wide
  11 inches (27.94 centimeters) High

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

capillus

We're all about hair

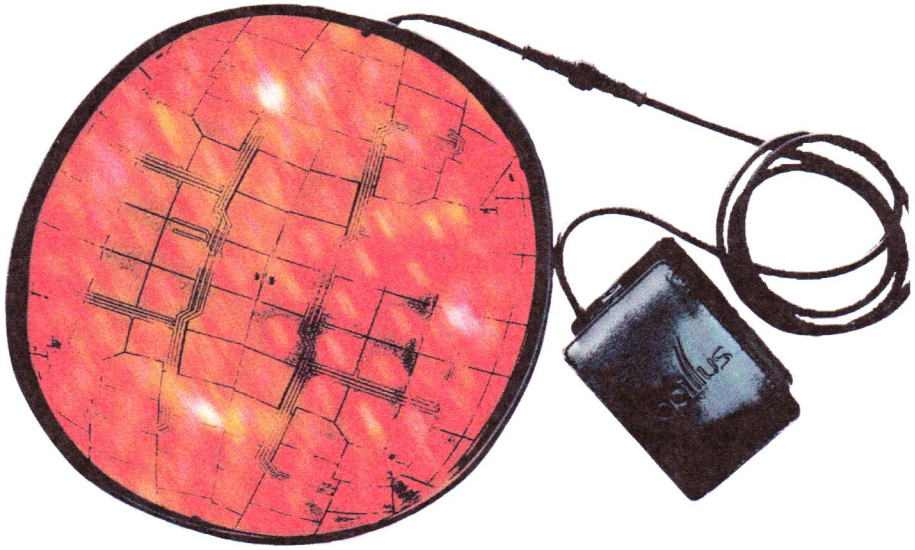
Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

capillus202

PRESCRIBED AND SOLD BY PHYSICIANS EVERYWHERE.

The Capillus202 is a portable dome-shaped device that is embedded with 202 laser diodes, each with 5mW of power. The device is worn under any hat of your preference for half an hour every other day, or as otherwise prescribed by your physician. Laser light in wavelengths of 650 nm is disseminated to the affected scalp, applying monochromatic red laser light.



This is an artist's rending of the proposed device and is not intended to depict the exact system and its components to be sold.

TECHNICAL SPECIFICATIONS

The Capillus202 includes the laser device, certified rechargeable battery pack, wall charger, sports cap, and carrying case, along with user manual.

CAPILLUS202 LASER DEVICE

- Number of Lasers: 202
- Diode Output: 5mw
- Laser Wavelength: 650 nm+/- 5nm

- Total Power: 1010 mW

PORTABLE BATTERY PACK

- Output: 11.1 V
- Total Capacity: 2200 mAh

WALL CHARGER

- Input: AC 100-240V
- Output: DC 12.6V 1A

WEAR IT ANY TIME, ANYWHERE. 30 MINUTES EVERY OTHER DAY.

Powered by a portable certified battery pack, the Capillus202 is easy to wear around the house or on your commute home. You decide when to use it: whether on your morning jog, on your drive home from work, while at your computer or even while sitting on the couch watching TV. There is no need for disruption from your everyday activities. And Capillus requires no extra hair washing or brushing. No messy creams. Just you... when and where you want to use it.

WHERE TO PURCHASE

The Capillus202 laser device, indicated to promote hair growth in adults with androgenic alopecia, is sold through our network of approved physicians. Order your Capillus202 laser device right from your physician. The Capillus202 retails for $1795.

WARRANTY

The Capillus202 is warranted against defects in materials or workmanship for a year from date of purchase. If the device is determined to be defective, the company will repair or replace it at no charge during the warranty period.

WWW.CAPILLUS.COM | 1 (888) 272-9599

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Section 13

Declaration of Conformity to required standards

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

DESIGN CONTROLS, PERFORMANCE TESTING, EMC, & ELECTRICAL SAFETY

As with the preceding (referenced) model, cleared under K143199:

We, Capillus LLC
(Company name)

1715 NW 82nd Avenue, Miami, FL 33126 USA
(address)

Declare under our responsibility that the product Capillus202

Capillus LLC
(brand name)

Capillus202
(Type version or model)

Laser Dome Hair Regrowth System
(product description)

to which this declaration relates is in conformity with the following harmonized standards:

EN60335-1:2002 + A1:2004 + A2:2006
EN60335-2-23:2003 5.0 Ed+ Corr. 2:2008 + A1:2008
EN62233: 2008
EN55014-1: 2006+ A1:2009 +A2:2011 EN55014-2:1997+A1:2001+ A2:2008
EN61000-3-2: 2006
EN61000-3-3: 2008
EN60825-1:2007-03

And is produced under a quality scheme at least in conformity with 21 CFR 820, QSR. Design Controls, 21 CFR 820.30 are followed and all appropriate documents are available for review, e.g. device master record, and device history records, etc.

As required by risk analysis (according to ISO 14971), all necessary verification and validation activities have been completed with appropriate outcome as defined by acceptance criteria. No new safety issues were identified as a result of this modification.

Signature, Patricia Schnoor, Quality Manager

December 16, 2015
Date

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Section 14

Software and Validation

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

SOFTWARE AND VALIDATION

The Capillus202 has an analog controlled, class 3R laser system and does not use microprocessors or software of any kind.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Section 15

Sterilization and Shelf Life

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

STERILIZATION AND SHELF LIFE

The device(s) do not require sterilization nor do they have a shelf life, therefore this topic does not apply.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Section 16

Biocompatibility

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

BIOCOMPATIBILITY

The materials used in the Capillus202 are exactly the same as for Capillus272 Pro cleared under K143199.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

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)*
K153618

Device Name
Capillus202

Indications for Use *(Describe)*
The Capillus202 is indicated to promote hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications of I-II, and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Section 6

Special 510(k) Summary

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Special 510(k) Summary

Capillus, LLC

Date Revised: **January 13, 2016**

Submitter's Contact Information:

Name: Patricia Schnoor

Address: Capillus LLC
1715 NW 202nd Avenue
Miami, FL 33126

Estab't Reg# 3010123655

Telephone: (786) 888-1874
Facsimile: (305) 418-7581

Name of Device and Name / Address of Sponsor:

Trade Name: Capillus202

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

Classification Name: Infrared lamp per 21 CFR 890.5500

Classification Code: OAP (Laser, Comb, Hair)

Sponsor Contact Information: Patricia Schnoor
Capillus LLC
1715 NW 82nd Avenue
Miami, FL 33126

Telephone: (786) 888-1874

Predicate Devices:

Device Trade Name	Manufacturer	510(k)
Capillus272 Pro	Capillus LLC	143199
LaserCap LCPro	Transdermal Cap, Inc	150613

Reference Devices:

Device Trade Name	Manufacturer
Hairmax Lasercomb	Lexington International

Intended Use / Indications for Use:

The Capillus202 is indicated to promote hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications of I-II, and with Fitzpatrick Skin Phototypes I-IV.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Technological Characteristics

The Capillus202 is exactly the same as the Capillus272 Pro in every way **except** the following:

1. **The Capillus202 has fewer diodes – 202 compared to 272 for Capillus272 Pro**

The Capillus272 Pro consists of 272 red, visible light, diode lasers operating at 650 nanometers, configured within an outer helmet and protective inner liner, and configured for portable use with rechargeable battery and adapter. The Capillus202 consists of 202 red, visible light, diode lasers operating at 650 nanometers, configured within an outer helmet and protective inner liner, and configured for portable use with rechargeable battery and adapter.

Just as for the previous version, the helmet system will automatically pause therapy if the subject's head is moved outside of the zone of radiation and will resume therapy when the correct head position is re-established. This is achieved by a safety interlock. At the beginning and end of a therapy session, audible tones are delivered to the user, indicating that therapy has begun (2 beeps) or ended (one long beep). The system is powered by rechargeable Nickel Metal Hydride battery cells assembled into a proprietary battery pack. Both the battery pack and charger are fully compliant to recognized, international standards.

Design Control Activities:

The Capillus design and development team followed ANSI/AAMI/ISO 14971:2007/(R)2010 Risk Management: Medical devices – Application of risk management to medical devices. Significant changes included assessing the effect a reduction of lasers would have on the end product, both for safety and for efficacy. All residual risks are found acceptable and the risk management file and summary are available for review. Based on the Capillus272 Pro, the verification and validation activities remain the same (e.g. output of each laser, operation of safety interface, and output of power pack), and were performed and assessed by designated personnel qualified to perform such activities. All methods, tests, and acceptance criteria are stipulated on the verification and validation reports. All documents are available for review.

Safety ratings remained the same; there was no change to the output of the individual lasers (≤ 5mW); however, the "dose" (total delivered energy/cm2) is reduced due to reduced number of lasers. This may affect efficacy; this observation is made based on the performance of other devices similar to Capillus that are currently cleared under device code OAP and utilize much fewer than 272 lasers (The closest equivalent in light sources is Transdermal with a total of 224 lasers).

Use instructions do not change. Indications for use and the dose schedule remain exactly the same as for Capillus272 Pro and as for other devices in the same category (product code OAP); which is for maximum 30 minutes, every other day.

The output of the laser diodes was verified to remain the same (each diode) as for the previous model. Design control activities were followed per 21 CFR 820.30:

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

a) **General: The Capillus LLC Quality Management System is compliant to the requirement of the quality system regulation and specifically to design controls as stipulated by 21 CFR 820.30.**

b) **Design and development planning:** During project planning activities, the risks were identified and assessed with respect to the proposed design change. The proposed design change was minimal and affected only the number of diodes in the PCB array. The power pack remains exactly the same. Review of the risk assessment from previous model revealed no significant changes or risks are identified for the new model Capillus202. Vigilance activities for the Capillus272 Pro indicated that there were no significant problems identified (no adverse events reported).

c) **Design input:** Design requirements for the Capillus272 Pro are transferred to the Capillus202 and an input/output matrix completed as for the original project.

d) **Design output:** Design requirements for the Capillus272 Pro are transferred to the Capillus202 and an input/output matrix completed as for the original project. Design outputs are verified per performance tests.

e) **Design review:** Appropriate design reviews were conducted; in this case (due to minimal change), a technical evaluation, and a verification of inputs and outputs (physical values) were completed.

f) **Design verification:** All verification activities to assess the impact of the change (reduction of number of laser diodes) were completed. Laser diode output remains the same, but total dosage is reduced. Since the cap is intended to be used indefinitely (if treatment is stopped, results are lost – see instructions for use), this will likely affect only the time required to witness the same result as achieved with the Capillus272 Pro. The Capillus202 is offered as a lower-cost alternative.

g) **Design validation:** Feedback from hair restoration specialists and consumers indicate that a lower-cost alternative is desired. The slower efficacy is accepted, with the understanding that treatment is intended to be indefinite.

h) **Design transfer:** The Capillus family of products are manufactured on-site in the factory in Miami. Design transfer was minimal; training requirement to the new PCB was minimal, and all other components (including overall build) remained the same.

i) **Design changes:** The design of all models follows our established design control, change control, document control procedures.

j) **Design history:** The design history file for the Capillus202 is available for review.

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Performance Data:

All verification and validation activities were performed by designated individuals. The results (available for review) demonstrate that the predetermined acceptance criteria were met.

Performance testing was conducted to confirm compliance to design specifications; all functions have been verified to operate as designed. All acceptance criteria were met by the device.

The Capillus202 conforms to the standard IEC-602025-2007-03; This IEC standard is a recognized and accepted standard by the FDA. The guidance document for this accepted standard is found in the Federal register. July 26, 2001 (volume 66, Number 144) [page 39049 39050]. This report validates for the Capillus202 the laser class of 3R which establishes the AEL (accessible emission limits) as 5 milliWatts maximum. The charger conforms to IEC 61959.

The performance data available for review demonstrates that the Capillus202 has exactly the same laser wavelength, output power (per diode), output beam, energy type, laser field, and treatment area as the original Capillus272 Pro cleared under K143199. Total "dose" – delivered energy over time - (J/cm^2) is logically reduced. Just as for Capillus272 Pro (K143199) and reference devices, there are no reported adverse events for this technology.

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Substantial Equivalence

The Capillus202 is the same technology used by Capillus272 Pro (K143199) and other reference devices; specifically, Transdermal Cap (K150613). .The Capillus202 is as safe and (commensurate to number of diodes) effective as the Capillus272 Pro, as well as other reference devices in its class, such as the Hairmax Lasercomb.

Capillus272 Pro	Capillus202	LaserCap LCPro
K143199	Candidate	K150613
LLLT Device Type	LLLT Device Type	LLLT Device Type
Prescription Use	Prescription Use	Prescription Application
Intended Use - Androgenic Alopecia	Intended Use - Androgenic Alopecia	Intended Use -Androgenic Alopecia
Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class3R
Helmet/Cap Design	Helmet/Cap Design	Helmet/Cap Design
650nm	650nm	650nm
Marketing clearance for Females	Marketing clearance for Females	Marketing clearance for both genders
Passive Use-Hands Free	Passive Use-Hands Free	Passive Use-Hands-Free
272 Laser Diodes	202 Laser Diodes	224 Laser Diodes
OAP Classification	OAP Classification	OAP Classification
Classification Name -Infrared Lamp	Classification Name -Infrared Lamp	Classification Name - Infrared Lamp
Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non- Heating
General & Plastic Surgery Committee	General & Plastic Surgery Committee	General & Plastic Surgery Committee
Fitzpatrick Skin Phototypes - I- IV	Fitzpatrick Skin Phototypes - I- IV	Fitzpatrick Skin Phototypes - I -IV
Ludwig-Savin I-II (females)	Ludwig-Savin I-II (females)	Ludwig-Savin I-II (females)
Efficacy Rates - High Compared to Placebo	Efficacy Rates - High Compared to Placebo	NA
Treatment- 17weeks, every other day (indefinite)	Treatment- 17weeks, every other day (indefinite)	Treatment - 16 weeks, every otherday (indefinite)
Device Class II	Device Class II	Device Class II

Capillus LLC believes that with the exception of the configuration of the optical elements, the Capillus202 is the same device in form, function, safety, and efficacy as the previous version and the predicate device(s). The Hairmax Lasercomb, offered as a reference, is proof of the functionality and acceptability of devices with fewer laser diodes cleared by the FDA in the category of OAP, both technically and clinically. Capillus LLC believes that the difference in the physical appearance, number of diodes, or in the method of delivering the radiant energy of the systems is of no consequence and does not affect the therapeutic value or the safety profile.

All compliant LLLT systems which use red light diode lasers are classified as class 3R laser systems by the IEC standard for allowable emission levels, which is a recognized standard by the FDA as well, and the adverse event profile is the same.

For these reasons, the Capillus202 satisfies the FDA's requirements (for device modification notification) with respect to intended use, and technological and design characteristics. Additionally, no new safety or efficacy concerns are

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raised due to the minor difference present between devices.

Signed:

01.13.2016

Patricia Schnoor

Quality, Safety & Compliance Manager

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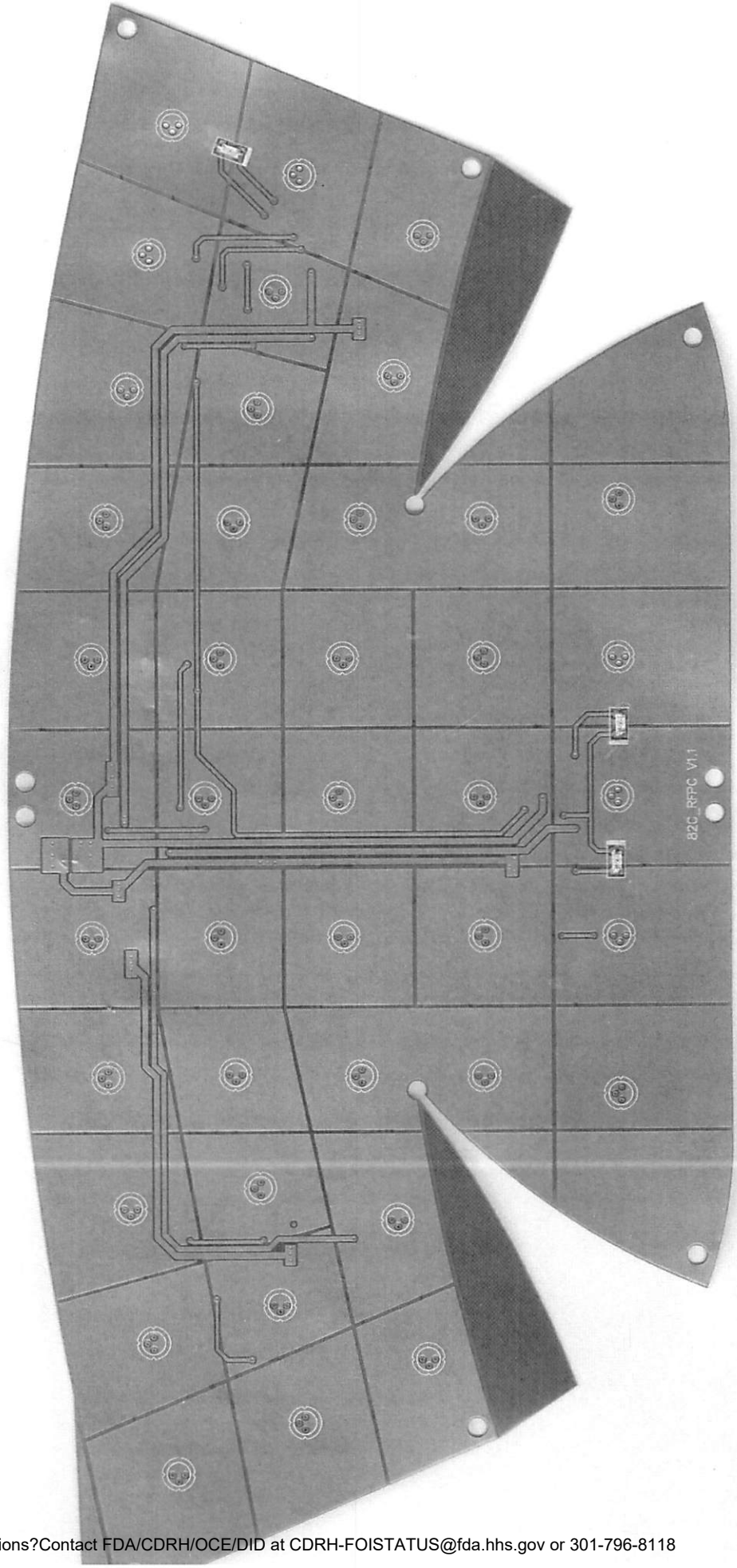

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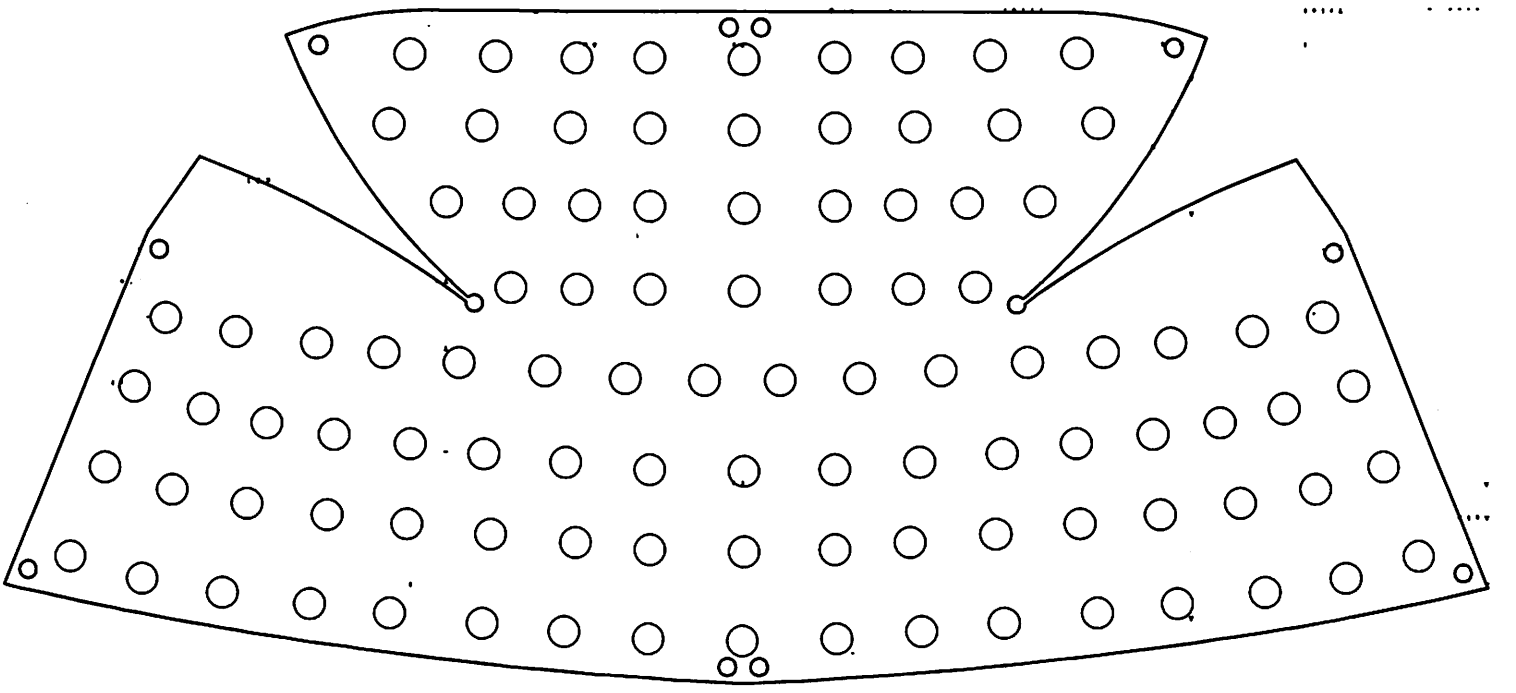

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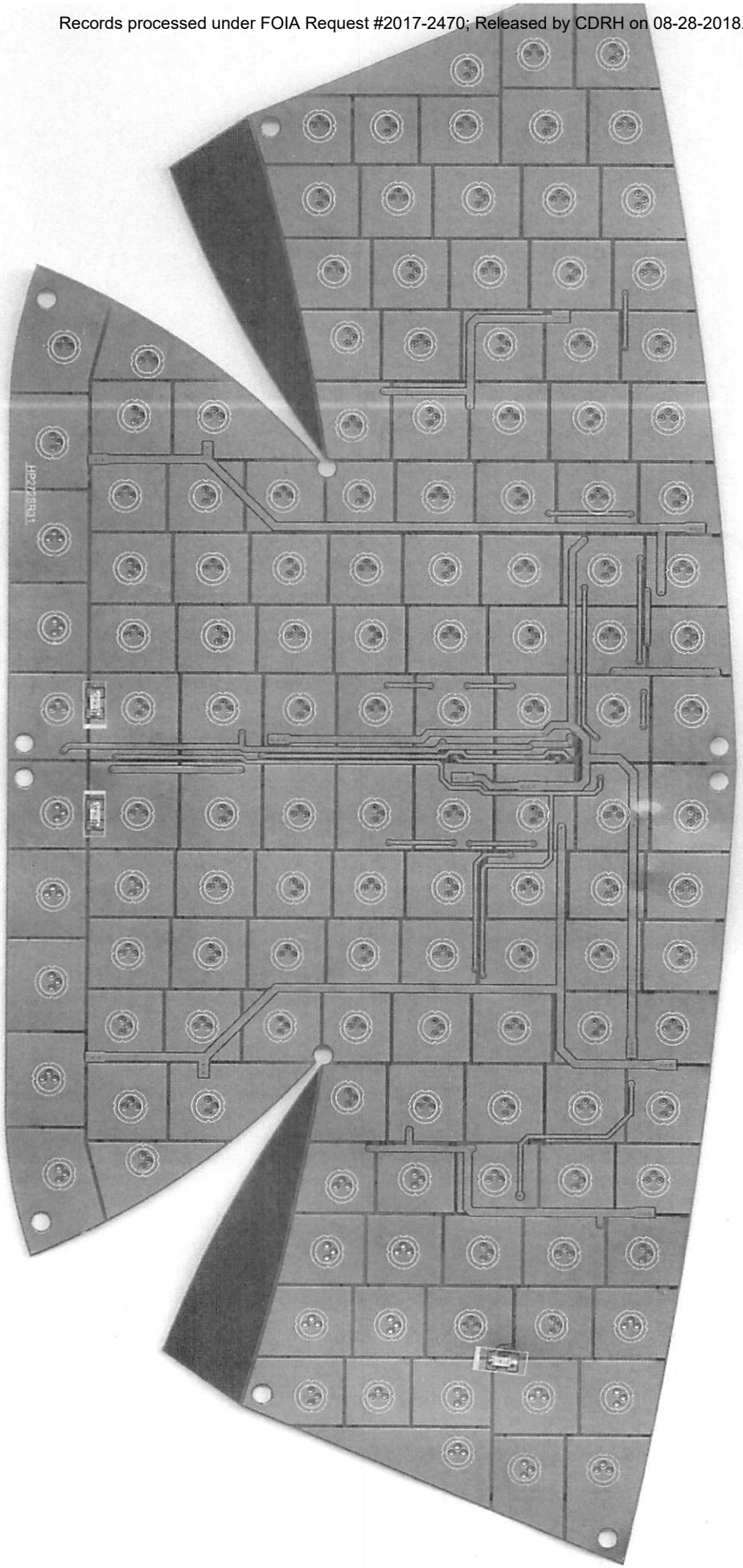

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See below the table for comparison of efficacy and calculation of expected efficacy:

PRODUCT

COMPANY

APPROVAL DATE

510(K) NUMBER

Sex

Study?

#Diodes/LEDs

Claimed efficacy

Calculation

HairMD

Trophy Skin, Inc.

11/16/2015

K152019

BOTH

N

21/30

UNK

OAP

Capillus 82

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Capillus LLC

8/21/2015

K151516

F

N

82

No Claim

OAP

LaserCap LC Pro / LC Elite

Transdermal Cap, Inc.

7/22/2015

K150613

F

N

224

No Claim

OAP

Capillus 272 OfficePro

Capillus LLC

6/9/2015

K150578

F

Y

272

51%

OAP

LX-100 Hair Growth Stimulation System

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Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Hairlabs International, Inc.

4/14/2015

K142824

90

No Claim

OAP
NHN

Capillus 272 Pro

Capillus LLC

1/29/2015

K143199

F

Y

272

51%

OAP

NUTRA STIM LASER COMB

NUTRA LUXE MD LLC

1/8/2015

K141588

F

N

12

No claim

OAP

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NUTRA STIM LASER COMB

NUTRA LUXE MD LLC

1/8/2015

K141596

M

N

12

No Claim

OAP

IGROW II HAIR GROWTH SYS

APIRA SCIENCE INC.

12/5/2014

K140931

F

Y

21/30

39%

OAP

HairMax LaserComb

LEXINGTON INTERNATIONAL LLC

12/1/2014

K142573

BOTH

N

41/0
82/0

No Claim
No Claim

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OAP

IGROW / IGROW II HAIR GROWTH SYS

APIRA SCIENCE INC.

8/21/2014

K141567

M

N

21/30

No Claim

OAP

SUNETICS CLINICAL BIO-STIM LASER

SUNETICS INTERNATIONAL LLC

12/20/2013

K132646

BOTH

N

UNK

No Claim

OAP
NHN

LASERBRUSH

SUNETICS INTERNATIONAL LLC

6/27/2013

K121920

BOTH

N

7/0
9/0
12/0

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No Claim

OAP

LASER HELMET

THERADOME INC.

6/14/2013

K122950

F

N

80/0

No Claim

OAP

IGROW II HAIR GROWTH SYS

APIRA SCIENCE INC.

12/5/2012

K122248

M

Y

21/30

39%

OAP

LASER HELMET

THERADOME INC.

3/2/2012

K113097

F

N

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OAP
NHN

HAIRMAX LASERCOMB

LEXINGTON INTERNATIONAL LLC

9/26/2011

K112524

F

N

OAP

HAIRMAX DUAL 12

LEXINGTON INTERNATIONAL LLC

8/16/2011

K111714

F

Y

OAP

HAIRMAX LASERCOMB

LEXINGTON INTERNATIONAL LLC

5/27/2011

K110233

NCT00981461

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HAIRMAX LASERCOMB

LEXINGTON INTERNATIONAL LLC

4/6/2011

K103368

M

Y

OAP

MEP-90 HAIR GROWTH SYSTEM

MIDWEST R.F. LLC.

2/23/2010

K091496

F

Y

OAP

HAIRMAX LASERCOMB

LEXINGTON INTERNATIONAL LLC

11/23/2009

K093499

M

N

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OAP
GEX

HAIRMAX LASERCOMB

LEXINGTON INTERNATIONAL LLC

1/18/2007

K060305

M

Y

OAP

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Thanks and best regards,

Patricia Schnoor
Quality, Safety, & Compliance Manager
Capillus LLC
1715 NW 82nd Ave
Miami, FL 33126
O: 786-888-1874
M: 305-255-3208
F: 305-418-7581
www.capillus.com<http://www.capillus.com/>

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From: Basu, Sankar [mailto:Sankar.Basu@fda.hhs.gov]
Sent: Monday, January 11, 2016 12:50 PM
To: Patricia Schnoor
<pschnoor@capillus.com<mailto:pschnoor@capillus.com>>
Subject: K153618--Capillus

Hi Patricia-

After talking with you I realized I forgot to ask you the following information:

Please furnish the information on the comparison of efficacy of all the predicate devices having 272, 224 and 82 lamps with the modified subject device having 202 lamps. Please also state how the efficacy is calculated.

You may add this response along with other responses already requested. Thank you.

Sankar Basu, Ph.D
Senior Physicist
FDA/CDRH/ODE/DSD/GSDB1
10903 New Hampshire Avenue
Silver Spring, MD 20993
(301)-796-6387 (t)
(301)-595-7851 (f)

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(b)(4)

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(b)(4)

[redacted]

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(b)(4)

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OAP

Thanks and best regards,

Patricia Schnoor
Quality, Safety, & Compliance Manager
Capillus LLC
1715 NW 82nd Ave
Miami, FL 33126
O: 786-888-1874
M: 305-255-3208
F: 305-418-7581
www.capillus.com<http://www.capillus.com/>

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

From: Basu, Sankar [mailto:Sankar.Basu@fda.hhs.gov]
Sent: Monday, January 11, 2016 12:50 PM
To: Patricia Schnoor
<pschnoor@capillus.com<mailto:pschnoor@capillus.com>>
Subject: K153618--Capillus

Hi Patricia-

After talking with you I realized I forgot to ask you the following information:

Please furnish the information on the comparison of efficacy of all the predicate devices having 272, 224 and 82 lamps with the modified subject device having 202 lamps. Please also state how the efficacy is calculated.

You may add this response along with other responses already requested. Thank you.

Sankar Basu, Ph.D
Senior Physicist
FDA/CDRH/ODE/DSD/GSDB1
10903 New Hampshire Avenue
Silver Spring, MD 20993
(301)-796-6387 (t)
(301)-595-7851 (f)

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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January 19, 2016</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Sankar Basu.

 *** This is a system-generated email notification ***

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

December 30, 2015</br></br>
Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K153618, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Sankar Basu.

 *** This is a system-generated email notification ***

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Special 510(k) Summary

Capillus. LLC

Date Revised: **January 13, 2016**

Submitter's Contact Information:

Name: Patricia Schnoor

Address: Capillus LLC
1715 NW 202nd Avenue
Miami, FL 33126

Estab't Reg# 3010123655

Telephone: (786) 888-1874
Facsimile: (305) 418-7581

Name of Device and Name / Address of Sponsor:

Trade Name: Capillus202

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

Classification Name: Infrared lamp per 21 CFR 890.5500

Classification Code: OAP (Laser, Comb, Hair)

Sponsor Contact Information: Patricia Schnoor
Capillus LLC
1715 NW 82nd Avenue
Miami, FL 33126

Telephone: (786) 888-1874

Predicate Devices:

Device Trade Name	Manufacturer	510(k)
Capillus272 Pro	Capillus LLC	143199
LaserCap LCPro	Transdermal Cap, Inc	150613

Reference Devices:

Device Trade Name	Manufacturer
Hairmax Lasercomb	Lexington International

Intended Use / Indications for Use:

The Capillus202 is indicated to promote hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications of I-II, and with Fitzpatrick Skin Phototypes I-IV.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Technological Characteristics

The Capillus202 is exactly the same as the Capillus272 Pro in every way **except** the following:

1. **The Capillus202 has fewer diodes – 202 compared to 272 for Capillus272 Pro**

The Capillus272 Pro consists of 272 red, visible light, diode lasers operating at 650 nanometers, configured within an outer helmet and protective inner liner, and configured for portable use with rechargeable battery and adapter. The Capillus202 consists of 202 red, visible light, diode lasers operating at 650 nanometers, configured within an outer helmet and protective inner liner, and configured for portable use with rechargeable battery and adapter.

Just as for the previous version, the helmet system will automatically pause therapy if the subject's head is moved outside of the zone of radiation and will resume therapy when the correct head position is re-established. This is achieved by a safety interlock. At the beginning and end of a therapy session, audible tones are delivered to the user, indicating that therapy has begun (2 beeps) or ended (one long beep). The system is powered by rechargeable Nickel Metal Hydride battery cells assembled into a proprietary battery pack. Both the battery pack and charger are fully compliant to recognized, international standards.

Design Control Activities:

The Capillus design and development team followed ANSI/AAMI/ISO 14971:2007/(R)2010 Risk Management: Medical devices – Application of risk management to medical devices. Significant changes included assessing the effect a reduction of lasers would have on the end product, both for safety and for efficacy. All residual risks are found acceptable and the risk management file and summary are available for review. Based on the Capillus272 Pro, the verification and validation activities remain the same (e.g. output of each laser, operation of safety interface, and output of power pack), and were performed and assessed by designated personnel qualified to perform such activities. All methods, tests, and acceptance criteria are stipulated on the verification and validation reports. All documents are available for review.

Safety ratings remained the same; there was no change to the output of the individual lasers (≤ 5mW); however, the "dose" (total delivered energy/cm2) is reduced due to reduced number of lasers. This may affect efficacy; this observation is made based on the performance of other devices similar to Capillus that are currently cleared under device code OAP and utilize much fewer than 272 lasers (The closest equivalent in light sources is Transdermal with a total of 224 lasers).

Use instructions do not change. Indications for use and the dose schedule remain exactly the same as for Capillus272 Pro and as for other devices in the same category (product code OAP); which is for maximum 30 minutes, every other day.

The output of the laser diodes was verified to remain the same (each diode) as for the previous model. Design control activities were followed per 21 CFR 820.30:

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018

a) **General: The Capillus LLC Quality Management System is compliant to the requirement of the quality system regulation and specifically to design controls as stipulated by 21 CFR 820.30.**

b) **Design and development planning:** During project planning activities, the risks were identified and assessed with respect to the proposed design change. The proposed design change was minimal and affected only the number of diodes in the PCB array. The power pack remains exactly the same. Review of the risk assessment from previous model revealed no significant changes or risks are identified for the new model Capillus202. Vigilance activities for the Capillus272 Pro indicated that there were no significant problems identified (no adverse events reported).

c) **Design input:** Design requirements for the Capillus272 Pro are transferred to the Capillus202 and an input/output matrix completed as for the original project.

d) **Design output:** Design requirements for the Capillus272 Pro are transferred to the Capillus202 and an input/output matrix completed as for the original project. Design outputs are verified per performance tests.

e) **Design review:** Appropriate design reviews were conducted; in this case (due to minimal change), a technical evaluation, and a verification of inputs and outputs (physical values) were completed.

f) **Design verification:** All verification activities to assess the impact of the change (reduction of number of laser diodes) were completed. Laser diode output remains the same, but total dosage is reduced. Since the cap is intended to be used indefinitely (if treatment is stopped, results are lost – see instructions for use), this will likely affect only the time required to witness the same result as achieved with the Capillus272 Pro. The Capillus202 is offered as a lower-cost alternative.

g) **Design validation:** Feedback from hair restoration specialists and consumers indicate that a lower-cost alternative is desired. The slower efficacy is accepted, with the understanding that treatment is intended to be indefinite.

h) **Design transfer:** The Capillus family of products are manufactured on-site in the factory in Miami. Design transfer was minimal; training requirement to the new PCB was minimal, and all other components (including overall build) remained the same.

i) **Design changes:** The design of all models follows our established design control, change control, document control procedures.

j) **Design history:** The design history file for the Capillus202 is available for review.

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Performance Data:

All verification and validation activities were performed by designated individuals. The results (available for review) demonstrate that the predetermined acceptance criteria were met.

Performance testing was conducted to confirm compliance to design specifications; all functions have been verified to operate as designed. All acceptance criteria were met by the device.

The Capillus202 conforms to the standard IEC-602025-2007-03; This IEC standard is a recognized and accepted standard by the FDA. The guidance document for this accepted standard is found in the Federal register. July 26. 2001 (volume 66, Number 144) [page 39049 39050]. This report validates for the Capillus202 the laser class of 3R which establishes the AEL (accessible emission limits) as 5 milliWatts maximum. The charger conforms to IEC 61959.

The performance data available for review demonstrates that the Capillus202 has exactly the same laser wavelength. output power (per diode), output beam, energy type, laser field, and treatment area as the original Capillus272 Pro cleared under K143199. Total "dose" – delivered energy over time - (J/cm^2) is logically reduced. Just as for Capillus272 Pro (K143199) and reference devices. there are no reported adverse events for this technology.

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Substantial Equivalence

The Capillus202 is the same technology used by Capillus272 Pro (K143199) and other reference devices: specifically, Transdermal Cap (K150613). The Capillus202 is as safe and (commensurate to number of diodes) effective as the Capillus272 Pro, as well as other reference devices in its class, such as the Hairmax Lasercomb.

Capillus272 Pro	Capillus202	LaserCap LCPro
K143199	Candidate	K150613
LLLT Device Type	LLLT Device Type	LLLT Device Type
Prescription Use	Prescription Use	Prescription Application
Intended Use - Androgenic Alopecia	Intended Use - Androgenic Alopecia	Intended Use -Androgenic Alopecia
Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class 3R	Contain Laser Diodes-Class3R
Helmet/Cap Design	Helmet/Cap Design	Helmet/Cap Design
650nm	650nm	650nm
Marketing clearance for Females	Marketing clearance for Females	Marketing clearance for both genders
Passive Use-Hands Free	Passive Use-Hands Free	Passive Use-Hands-Free
272 Laser Diodes	202 Laser Diodes	224 Laser Diodes
OAP Classification	OAP Classification	OAP Classification
Classification Name -Infrared Lamp	Classification Name -Infrared Lamp	Classification Name - Infrared Lamp
Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non- Heating
General & Plastic Surgery Committee	General & Plastic Surgery Committee	General & Plastic Surgery Committee
Fitzpatrick Skin Phototypes - I- IV	Fitzpatrick Skin Phototypes - I- IV	Fitzpatrick Skin Phototypes - I -IV
Ludwig-Savin I-II (females)	Ludwig-Savin I-II (females)	Ludwig-Savin I-II (females)
Efficacy Rates - High Compared to Placebo	Efficacy Rates - High Compared to Placebo	NA
Treatment- 17weeks, every other day (indefinite)	Treatment- 17weeks, every other day (indefinite)	Treatment - 16 weeks, every otherday (indefinite)
Device Class II	Device Class II	Device Class II

Capillus LLC believes that with the exception of the configuration of the optical elements, the Capillus202 is the same device in form, function, safety, and efficacy as the previous version and the predicate device(s). The Hairmax Lasercomb, offered as a reference, is proof of the functionality and acceptability of devices with fewer laser diodes cleared by the FDA in the category of OAP, both technically and clinically. Capillus LLC believes that the difference in the physical appearance, number of diodes, or in the method of delivering the radiant energy of the systems is of no consequence and does not affect the therapeutic value or the safety profile.

All compliant LLLT systems which use red light diode lasers are classified as class 3R laser systems by the IEC standard for allowable emission levels, which is a recognized standard by the FDA as well, and the adverse event profile is the same.

For these reasons, the Capillus202 satisfies the FDA's requirements (for device modification notification) with respect to intended use, and technological and design characteristics. Additionally, no new safety or efficacy concerns are

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raised due to the minor difference present between devices.

Signed:

01-13-2016

Patricia Schnoor

Quality, Safety & Compliance Manager

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

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)*
K153618

Device Name
Capillus202

Indications for Use *(Describe)*
The Capillus202 is indicated to promote hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications of I-II, and 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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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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

January 19, 2016

Capillus LLC
Ms. Patricia Schnoor
Manager, Quality & Regulatory Affairs
1715 Northwest 82nd Avenue
Miami, Florida 33126

Re: K153618
Trade/Device Name: Capillus202
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: December 16, 2015
Received: December 18, 2015

Dear Schnoor:

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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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" (21CFR 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,

Jennifer R. Stevenson -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

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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

January 19, 2016

Capillus LLC
Ms. Patricia Schnoor
Manager, Quality & Regulatory Affairs
1715 Northwest 82nd Avenue
Miami, Florida 33126

Re: K153618
Trade/Device Name: Capillus202
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: December 16, 2015
Received: December 18, 2015

Dear Schnoor:

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Sincerely yours,

Jennifer R. Stevenson -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

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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)*
K153618

Device Name
Capillus202

Indications for Use *(Describe)*
The Capillus202 is indicated to promote hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications of I-II, and with Fitzpatrick Skin Phototypes I-IV.

Type of Use *(Select one or both, as applicable)*

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Special 510(k) Summary

Capillus. LLC

Date Revised: **January 13, 2016**

Submitter's Contact Information:

Name: Patricia Schnoor

Address: Capillus LLC
1715 NW 202nd Avenue
Miami, FL 33126

Estab't Reg# 3010123655

Telephone: (786) 888-1874
Facsimile: (305) 418-7581

Name of Device and Name / Address of Sponsor:

Trade Name: Capillus202

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

Classification Name: Infrared lamp per 21 CFR 890.5500

Classification Code: OAP (Laser, Comb, Hair)

Sponsor Contact Information: Patricia Schnoor
Capillus LLC
1715 NW 82nd Avenue
Miami, FL 33126

Telephone: (786) 888-1874

Predicate Devices:

Device Trade Name	Manufacturer	510(k)
Capillus272 Pro	Capillus LLC	143199
LaserCap LCPro	Transdermal Cap, Inc	150613

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Use instructions do not change. Indications for use and the dose schedule remain exactly the same as for Capillus272 Pro and as for other devices in the same category (product code OAP); which is for maximum 30 minutes, every other day.

The output of the laser diodes was verified to remain the same (each diode) as for the previous model. Design control activities were followed per 21 CFR 820.30:

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

a) **General: The Capillus LLC Quality Management System is compliant to the requirement of the quality system regulation and specifically to design controls as stipulated by 21 CFR 820.30.**

b) **Design and development planning:** During project planning activities, the risks were identified and assessed with respect to the proposed design change. The proposed design change was minimal and affected only the number of diodes in the PCB array. The power pack remains exactly the same. Review of the risk assessment from previous model revealed no significant changes or risks are identified for the new model Capillus202. Vigilance activities for the Capillus272 Pro indicated that there were no significant problems identified (no adverse events reported).

c) **Design input:** Design requirements for the Capillus272 Pro are transferred to the Capillus202 and an input/output matrix completed as for the original project.

d) **Design output:** Design requirements for the Capillus272 Pro are transferred to the Capillus202 and an input/output matrix completed as for the original project. Design outputs are verified per performance tests.

e) **Design review:** Appropriate design reviews were conducted; in this case (due to minimal change), a technical evaluation, and a verification of inputs and outputs (physical values) were completed.

f) **Design verification:** All verification activities to assess the impact of the change (reduction of number of laser diodes) were completed. Laser diode output remains the same, but total dosage is reduced. Since the cap is intended to be used indefinitely (if treatment is stopped, results are lost – see instructions for use), this will likely affect only the time required to witness the same result as achieved with the Capillus272 Pro. The Capillus202 is offered as a lower-cost alternative.

g) **Design validation:** Feedback from hair restoration specialists and consumers indicate that a lower-cost alternative is desired. The slower efficacy is accepted, with the understanding that treatment is intended to be indefinite.

h) **Design transfer:** The Capillus family of products are manufactured on-site in the factory in Miami. Design transfer was minimal; training requirement to the new PCB was minimal, and all other components (including overall build) remained the same.

i) **Design changes:** The design of all models follows our established design control, change control, document control procedures.

j) **Design history:** The design history file for the Capillus202 is available for review.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018

Performance Data:

All verification and validation activities were performed by designated individuals. The results (available for review) demonstrate that the predetermined acceptance criteria were met.

Performance testing was conducted to confirm compliance to design specifications: all functions have been verified to operate as designed. All acceptance criteria were met by the device.

The Capillus202 conforms to the standard IEC-602025-2007-03; This IEC standard is a recognized and accepted standard by the FDA. The guidance document for this accepted standard is found in the Federal register. July 26, 2001 (volume 66, Number 144) [page 39049 39050]. This report validates for the Capillus202 the laser class of 3R which establishes the AEL (accessible emission limits) as 5 milliWatts maximum. The charger conforms to IEC 61959.

The performance data available for review demonstrates that the Capillus202 has exactly the same laser wavelength, output power (per diode), output beam, energy type, laser field, and treatment area as the original Capillus272 Pro cleared under K143199. Total "dose" – delivered energy over time - (J/cm^2) is logically reduced. Just as for Capillus272 Pro (K143199) and reference devices, there are no reported adverse events for this technology.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Substantial Equivalence

The Capillus202 is the same technology used by Capillus272 Pro (K143199) and other reference devices; specifically, Transdermal Cap (K150613). The Capillus202 is as safe and (commensurate to number of diodes) effective as the Capillus272 Pro, as well as other reference devices in its class, such as the Hairmax Lasercomb.

Capillus272 Pro	Capillus202	LaserCap LCPro
K143199	Candidate	K150613
LLLT Device Type	LLLT Device Type	LLLT Device Type
Prescription Use	Prescription Use	Prescription Application
Intended Use - Androgenic Alopecia	Intended Use - Androgenic Alopecia	Intended Use -Androgenic Alopecia
Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class3R
Helmet/Cap Design	Helmet/Cap Design	Helmet/Cap Design
650nm	650nm	650nm
Marketing clearance for Females	Marketing clearance for Females	Marketing clearance for both genders
Passive Use-Hands Free	Passive Use-Hands Free	Passive Use-Hands-Free
272 Laser Diodes	202 Laser Diodes	224 Laser Diodes
OAP Classification	OAP Classification	OAP Classification
Classification Name -Infrared Lamp	Classification Name -Infrared Lamp	Classification Name - Infrared Lamp
Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non- Heating
General & Plastic Surgery Committee	General & Plastic Surgery Committee	General & Plastic Surgery Committee
Fitzpatrick Skin Phototypes - I- IV	Fitzpatrick Skin Phototypes - I- IV	Fitzpatrick Skin Phototypes - I -IV
Ludwig-Savin I-II (females)	Ludwig-Savin I-II (females)	Ludwig-Savin I-II (females)
Efficacy Rates - High Compared to Placebo	Efficacy Rates - High Compared to Placebo	NA
Treatment- 17weeks, every other day (indefinite)	Treatment- 17weeks, every other day (indefinite)	Treatment - 16 weeks, every otherday (indefinite)
Device Class II	Device Class II	Device Class II

Capillus LLC believes that with the exception of the configuration of the optical elements, the Capillus202 is the same device in form, function, safety, and efficacy as the previous version and the predicate device(s). The Hairmax Lasercomb, offered as a reference, is proof of the functionality and acceptability of devices with fewer laser diodes cleared by the FDA in the category of OAP, both technically and clinically. Capillus LLC believes that the difference in the physical appearance, number of diodes, or in the method of delivering the radiant energy of the systems is of no consequence and does not affect the therapeutic value or the safety profile.

All compliant LLLT systems which use red light diode lasers are classified as class 3R laser systems by the IEC standard for allowable emission levels, which is a recognized standard by the FDA as well, and the adverse event profile is the same.

For these reasons, the Capillus202 satisfies the FDA's requirements (for device modification notification) with respect to intended use, and technological and design characteristics. Additionally, no new safety or efficacy concerns are

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

raised due to the minor difference present between devices.

Signed:

01.13.2016

Patricia Schnoor

Quality, Safety & Compliance Manager

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

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)*
K153618

Device Name
Capillus202

Indications for Use *(Describe)*
The Capillus202 is indicated to promote hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications of I-II, and 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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Section 6

Special 510(k) Summary

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Special 510(k) Summary

Capillus, LLC

Date Revised: **January 13, 2016**

Submitter's Contact Information:

Name: Patricia Schnoor

Address: Capillus LLC
1715 NW 202nd Avenue
Miami, FL 33126

Estab't Reg# 3010123655

Telephone: (786) 888-1874
Facsimile: (305) 418-7581

Name of Device and Name / Address of Sponsor:

Trade Name: Capillus202

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

Classification Name: Infrared lamp per 21 CFR 890.5500

Classification Code: OAP (Laser, Comb. Hair)

Sponsor Contact Information: Patricia Schnoor
Capillus LLC
1715 NW 82nd Avenue
Miami, FL 33126

Telephone: (786) 888-1874

Predicate Devices:

Device Trade Name	Manufacturer	510(k)
Capillus272 Pro	Capillus LLC	143199
LaserCap LCPro	Transdermal Cap, Inc	150613

Reference Devices:

Device Trade Name	Manufacturer
Hairmax Lasercomb	Lexington International

Intended Use / Indications for Use:

The Capillus202 is indicated to promote hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications of I-II, and with Fitzpatrick Skin Phototypes I-IV.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Technological Characteristics

The Capillus202 is exactly the same as the Capillus272 Pro in every way **except** the following:

1. **The Capillus202 has fewer diodes – 202 compared to 272 for Capillus272 Pro**

The Capillus272 Pro consists of 272 red, visible light, diode lasers operating at 650 nanometers, configured within an outer helmet and protective inner liner, and configured for portable use with rechargeable battery and adapter. The Capillus202 consists of 202 red, visible light, diode lasers operating at 650 nanometers, configured within an outer helmet and protective inner liner, and configured for portable use with rechargeable battery and adapter.

Just as for the previous version, the helmet system will automatically pause therapy if the subject's head is moved outside of the zone of radiation and will resume therapy when the correct head position is re-established. This is achieved by a safety interlock. At the beginning and end of a therapy session, audible tones are delivered to the user, indicating that therapy has begun (2 beeps) or ended (one long beep). The system is powered by rechargeable Nickel Metal Hydride battery cells assembled into a proprietary battery pack. Both the battery pack and charger are fully compliant to recognized, international standards.

Design Control Activities:

The Capillus design and development team followed ANSI/AAMI/ISO 14971:2007/(R)2010 Risk Management: Medical devices – Application of risk management to medical devices. Significant changes included assessing the effect a reduction of lasers would have on the end product, both for safety and for efficacy. All residual risks are found acceptable and the risk management file and summary are available for review. Based on the Capillus272 Pro, the verification and validation activities remain the same (e.g. output of each laser, operation of safety interface, and output of power pack), and were performed and assessed by designated personnel qualified to perform such activities. All methods, tests, and acceptance criteria are stipulated on the verification and validation reports. All documents are available for review.

Safety ratings remained the same; there was no change to the output of the individual lasers (≤ 5mW); however, the "dose" (total delivered energy/cm2) is reduced due to reduced number of lasers. This may affect efficacy; this observation is made based on the performance of other devices similar to Capillus that are currently cleared under device code OAP and utilize much fewer than 272 lasers (The closest equivalent in light sources is Transdermal with a total of 224 lasers).

Use instructions do not change. Indications for use and the dose schedule remain exactly the same as for Capillus272 Pro and as for other devices in the same category (product code OAP); which is for maximum 30 minutes, every other day.

The output of the laser diodes was verified to remain the same (each diode) as for the previous model. Design control activities were followed per 21 CFR 820.30:

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

a) **General: The Capillus LLC Quality Management System is compliant to the requirement of the quality system regulation and specifically to design controls as stipulated by 21 CFR 820.30.**

b) **Design and development planning:** During project planning activities, the risks were identified and assessed with respect to the proposed design change. The proposed design change was minimal and affected only the number of diodes in the PCB array. The power pack remains exactly the same. Review of the risk assessment from previous model revealed no significant changes or risks are identified for the new model Capillus202. Vigilance activities for the Capillus272 Pro indicated that there were no significant problems identified (no adverse events reported).

c) **Design input:** Design requirements for the Capillus272 Pro are transferred to the Capillus202 and an input/output matrix completed as for the original project.

d) **Design output:** Design requirements for the Capillus272 Pro are transferred to the Capillus202 and an input/output matrix completed as for the original project. Design outputs are verified per performance tests.

e) **Design review:** Appropriate design reviews were conducted; in this case (due to minimal change), a technical evaluation, and a verification of inputs and outputs (physical values) were completed.

f) **Design verification:** All verification activities to assess the impact of the change (reduction of number of laser diodes) were completed. Laser diode output remains the same, but total dosage is reduced. Since the cap is intended to be used indefinitely (if treatment is stopped, results are lost – see instructions for use), this will likely affect only the time required to witness the same result as achieved with the Capillus272 Pro. The Capillus202 is offered as a lower-cost alternative.

g) **Design validation:** Feedback from hair restoration specialists and consumers indicate that a lower-cost alternative is desired. The slower efficacy is accepted, with the understanding that treatment is intended to be indefinite.

h) **Design transfer:** The Capillus family of products are manufactured on-site in the factory in Miami. Design transfer was minimal; training requirement to the new PCB was minimal, and all other components (including overall build) remained the same.

i) **Design changes:** The design of all models follows our established design control, change control, document control procedures.

j) **Design history:** The design history file for the Capillus202 is available for review.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Performance Data:

All verification and validation activities were performed by designated individuals. The results (available for review) demonstrate that the predetermined acceptance criteria were met.

Performance testing was conducted to confirm compliance to design specifications; all functions have been verified to operate as designed. All acceptance criteria were met by the device.

The Capillus202 conforms to the standard IEC-602025-2007-03; This IEC standard is a recognized and accepted standard by the FDA. The guidance document for this accepted standard is found in the Federal register. July 26, 2001 (volume 66, Number 144) [page 39049 39050]. This report validates for the Capillus202 the laser class of 3R which establishes the AEL (accessible emission limits) as 5 milliWatts maximum. The charger conforms to IEC 61959.

The performance data available for review demonstrates that the Capillus202 has exactly the same laser wavelength, output power (per diode), output beam, energy type, laser field, and treatment area as the original Capillus272 Pro cleared under K143199. Total "dose" – delivered energy over time - (J/cm^2) is logically reduced. Just as for Capillus272 Pro (K143199) and reference devices, there are no reported adverse events for this technology.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Substantial Equivalence

The Capillus202 is the same technology used by Capillus272 Pro (K143199) and other reference devices; specifically, Transdermal Cap (K150613). The Capillus202 is as safe and (commensurate to number of diodes) effective as the Capillus272 Pro, as well as other reference devices in its class, such as the Hairmax Lasercomb.

Capillus272 Pro	Capillus202	LaserCap LCPro
K143199	Candidate	K150613
LLLT Device Type	LLLT Device Type	LLLT Device Type
Prescription Use	Prescription Use	Prescription Application
Intended Use - Androgenic Alopecia	Intended Use - Androgenic Alopecia	Intended Use -Androgenic Alopecia
Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class3R
Helmet/Cap Design	Helmet/Cap Design	Helmet/Cap Design
650nm	650nm	650nm
Marketing clearance for Females	Marketing clearance for Females	Marketing clearance for both genders
Passive Use-Hands Free	Passive Use-Hands Free	Passive Use-Hands-Free
272 Laser Diodes	202 Laser Diodes	224 Laser Diodes
OAP Classification	OAP Classification	OAP Classification
Classification Name -Infrared Lamp	Classification Name -Infrared Lamp	Classification Name - Infrared Lamp
Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non- Heating
General & Plastic Surgery Committee	General & Plastic Surgery Committee	General & Plastic Surgery Committee
Fitzpatrick Skin Phototypes - I- IV	Fitzpatrick Skin Phototypes - I- IV	Fitzpatrick Skin Phototypes - I -IV
Ludwig-Savin I-II (females)	Ludwig-Savin I-II (females)	Ludwig-Savin I-II (females)
Efficacy Rates - High Compared to Placebo	Efficacy Rates - High Compared to Placebo	NA
Treatment- 17weeks, every other day (indefinite)	Treatment- 17weeks, every other day (indefinite)	Treatment - 16 weeks, every otherday (indefinite)
Device Class II	Device Class II	Device Class II

Capillus LLC believes that with the exception of the configuration of the optical elements, the Capillus202 is the same device in form, function, safety, and efficacy as the previous version and the predicate device(s). The Hairmax Lasercomb, offered as a reference, is proof of the functionality and acceptability of devices with fewer laser diodes cleared by the FDA in the category of OAP, both technically and clinically. Capillus LLC believes that the difference in the physical appearance, number of diodes, or in the method of delivering the radiant energy of the systems is of no consequence and does not affect the therapeutic value or the safety profile.

All compliant LLLT systems which use red light diode lasers are classified as class 3R laser systems by the IEC standard for allowable emission levels, which is a recognized standard by the FDA as well, and the adverse event profile is the same.

For these reasons, the Capillus202 satisfies the FDA's requirements (for device modification notification) with respect to intended use, and technological and design characteristics. Additionally, no new safety or efficacy concerns are

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

raised due to the minor difference present between devices.

Signed:

01.13.2016

Patricia Schnoor

Quality, Safety & Compliance Manager

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018

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

Capillus LLC
Ms. Patricia Schnoor
Manager, Quality & Regulatory Affairs
1715 Northwest 82nd Avenue
Miami, Florida 33126

Re: K153618
Trade/Device Name: Capillus202
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: December 16, 2015
Received: December 18, 2015

Dear Schnoor:

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 [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and 809]); medical device reporting (reporting of medical device-related adverse events) (21 CFR

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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" (21CFR 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,

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

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Special 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K153618 Date Received by DCC: Dec 18, 2015

Lead Reviewer: Sankar (Bose) Basu

Branch: GSDB1 Division: DSD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during the substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Special 510(k) Criteria

The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

	Yes	No
1) 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	X	
Comments:		
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	X	
Comments:		
3) Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).	X	
Comments:		
4) The submission includes only summary-level information (i.e., NO test reports with performance data). *Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.*	X	
Comments:		

Does the submission meet all 4 criteria above?

- (●) Yes, submission meets criteria for a Special 510(k). Continue checklist below.
- ( ) No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist, convert to a Traditional and apply the Traditional checklist.

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special)	X		

Comments: Special 510(k) is identified in the submission

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name	X				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X				
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended* format. *(http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*	X				
4) Submission contains a 510(k) Summary or 510(k) Statement.	X				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm)*	X				
6) Submission is a Class III 510(k) device.			X		
7) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	X				
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.			X		
B. Device Description					
8) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.			X		
9) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	X				
10) The submission includes descriptive information for the device, including the following:					
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	X				
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X				
c) A list and description of each device for which clearance is requested.	X				

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	X				
11) A description of all device modification(s) including rationale for each modification.	X				
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.	X				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X				
b) Submission includes a description (as detailed in item 10(a), 10(b) and 10(d) above) of each component or accessory.	X				
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	X				
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm)*	X				
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	X				
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
a) Indications for Use	X				
b) Technology, including features, materials, and principles of operation	X				
D. Design Control Activities					
15) Design Control Activities Summary includes all of the following:					

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components **AND** the results of the analysis.	X				
b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.	X				
c) Declaration of conformity with design controls. All 3 must be present to answer "Yes." i. Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met. ii. Statement that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30. iii. Statement is signed by the individual responsible for these activities.	X				
E. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
16) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	X				
a) All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	X				
17) Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).	X				

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Decision: ◉ Accept ○ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Sankar P. Basu -S Digitally signed by Sankar P. Basu -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sankar P. Basu -S, 0.9.2342.19200300.100.1.1=1300054169 Date: 2015.12.29 14:26:45 -05'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with with decision required. Branch and Division digital signature optional.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K_153618_

Date: January 15, 2016
To: The Record
From: Sankar (Bose) Basu, Ph.D

Office: ODE

Division: DSD

510(k) Holder: Capillus, LLC
Device Name: Capillus 202
Contact: Patricia Schnoor
Phone: (786)-888-1874
Fax: (305)-418-7581
Email: pschnoor@ capillus.com

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce Capillus 202 into interstate commerce by submitting this Special 510(k) application. The sponsor previously received clearance for similar device with 272 LED elements under K143199. This time they would like to modify the same device by removing 75 LED elements and made it with 202 LED lamps. The technological characteristics remain unchanged and so does the indications for use.
The lead reviewer is recommending SESE for this modified device since predicate devices exist with number of LED lamps ranging between 7 and 224 of same wavelength (650 nm). Therefore, no safety or efficacy concerns exist for devices containing 202 LED lights.

II. Device Description :

The Capillus202 is a low-level laser/light system operating at 650 nanometers. The physical configuration is that of a helmet or baseball cap containing an inner and outer shell. The system operates from a battery pack, which is charged by an adapter. This configuration permits mobility during therapy sessions. The adapter operates on line voltages from 110 to 260 volts; the device will not operate while charging. The helmet's inner liner permits full adjustment to any head shape by means of semi-rigid, conforming materials. The helmet contains 202, **5 milli-Watt (mW)** laser diodes that emit red (visible) light. This system delivers fixed laser emission levels as defined by the diode characteristics, which cannot be altered by the operator.

The device helmet is constructed of a biocompatible class of plastic – exactly the same material as is used for the Capillus272 Pro. The Capillus202 is a hands-free system, requiring no active processes by the user, other than starting a therapy session. The laser light reaches the human scalp, emitted directly from behind the clear inner liner, without any

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focusing lens system. The device helmet covers the upper one-third of the head, with orientation from the bridge of the nose in the anterior, toward the occipital notch in the posterior and from the upper most portion of the ear on both sides of the head. When operated correctly, the helmet remains approximately 1-2 centimeters (depending on head shape/size) from the scalp.

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

III. Indications for Use

The Capillus 202 is indicated for use to promote hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications I –II and with Fitzpatrick skin photo-types I to IV.

IV. Predicate Device Comparison

The intended use and the technological characteristics are the same except the number of lamps used in the predicate device is less but falls in the ranges that are cleared by the agency. The efficacy of the cleared lamps ranges between 39 to 51%.

V. Labeling

Labeling has been provided which includes instructions for use and an appropriate prescription statement as required by CFR 21.807.87 (e).

The labeling is the same as used in the predicate device but the number of lamps used is somewhat different which is shown in the labeling provided in the User Manual.
The recommended treatment time is 30 min each day on alternate days and the duration of treatment is recommended by the physician. At any rate the significant improvement can be noticed in 4 weeks.

VI. Sterilization/Shelf Life/Reuse : N/A

VII. Biocompatibility : Same as in the predicate unmodified device

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VIII. Software : N/A

Version:		
Level of Concern:		
	Yes	**No**
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

IX. Substantial Equivalence Discussion

Some 70 lamps were removed to make the device cheaper in price but although this may compromise efficacy of the device somewhat but the final efficacy ranges between the efficacy of the lamps cleared, i.e., between 39 to 51%.

The sponsor was asked to present a drawing of the PCB array of lamps used both in the predicate and subject devices. The drawings presented by the sponsor demonstrate that the lamps removed in the subject device are all in the boundary regions or uppermost region by the side of the ear, and not from the core region extending from the bridge of the nose in the anterior to the occipital notch in the posterior region.

Low level LED lights of 5 mW of power are not supposed to cause any safety concerns for either of the subject or predicate devices.

See the table below for comparison of efficacy and calculation of expected efficacy along with the different number of LEDs in different predicate devices:

PRODUCT	COMPANY	APPROVAL DATE	510(K) NUMBER	Sex	Study?	#Diodes/LEDs	Claimed efficacy	Calculation
HairMD	Trophy Skin, Inc.	11/16/2015	K152019	BOTH	N	21/30	UNK	OAP
Capillus 82	Capillus LLC	8/21/2015	K151516	F	N	82	No Claim	OAP
LaserCap LC Pro / LC Elite	Transdermal Cap, Inc.	7/22/2015	K150613	F	N	224	No Claim	OAP
Capillus 272 OfficePro	Capillus LLC	6/9/2015	K150578	F	Y	272	51%	OAP
LX-100 Hair Growth Stimulation System	Hairlabs International, Inc.	4/14/2015	K142824			90	No Claim	OAP NHN
Capillus 272 Pro	Capillus LLC	1/29/2015	K143199	F	Y	272	51%	OAP

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NUTRA STIM LASER COMB	NUTRA LUXE MD LLC	1/8/2015	K141588	F	N	12	No claim	OAP
NUTRA STIM LASER COMB	NUTRA LUXE MD LLC	1/8/2015	K141596	M	N	12	No Claim	OAP
IGROW II HAIR GROWTH SYS	APIRA SCIENCE INC.	12/5/2014	K140931	F	Y	21/30	39%	OAP
HairMax LaserComb	LEXINGTON INTERNATIONAL LLC	12/1/2014	K142573	BOTH	N	41/0 82/0	No Claim No Claim	OAP
IGROW / IGROW II HAIR GROWTH SYS	APIRA SCIENCE INC.	8/21/2014	K141567	M	N	21/30	No Claim	OAP
SUNETICS CLINICAL BIO-STIM LASER	SUNETICS INTERNATIONAL LLC	12/20/2013	K132646	BOTH	N	UNK	No Claim	OAP NHN
LASERBRUSH	SUNETICS INTERNATIONAL LLC	6/27/2013	K121920	BOTH	N	7/0 9/0 12/0	No Claim	OAP
LASER HELMET	THERADOME INC.	6/14/2013	K122950	F	N	80/0	No Claim	OAP
IGROW II HAIR GROWTH SYS	APIRA SCIENCE INC.	12/5/2012	K122248	M	Y	21/30	39%	OAP
LASER HELMET	THERADOME INC.	3/2/2012	K113097	F	N			OAP NHN
HAIRMAX LASERCOMB	LEXINGTON INTERNATIONAL LLC	9/26/2011	K112524	F	N			OAP
HAIRMAX DUAL 12	LEXINGTON INTERNATIONAL LLC	8/16/2011	K111714	F	Y			OAP
HAIRMAX LASERCOMB	LEXINGTON INTERNATIONAL LLC	5/27/2011	K110233		NCT00981461			
HAIRMAX LASERCOMB	LEXINGTON INTERNATIONAL LLC	4/6/2011	K103368	M	Y			OAP
MEP-90 HAIR GROWTH SYSTEM	MIDWEST R.F. LLC.	2/23/2010	K091496	F	Y			OAP
HAIRMAX LASERCOMB	LEXINGTON INTERNATIONAL LLC	11/23/2009	K093499	M	N			OAP GEX
HAIRMAX LASERCOMB	LEXINGTON INTERNATIONAL LLC	1/18/2007	K060305	M	Y			OAP

IX. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety :

This type of safety has been addressed in the predicate unmodified device and electrical and mechanical safety of the modified device are found to be identical.

X. Performance Testing – Bench :

(b) (4)

[redacted]

XII. Performance Testing – Animal : N/A

XIII. Performance Testing – Clinical : N/A

	YES	NO	
1. Is the predicate device legally marketed?	X		If **YES** = Go to 2 If **NO** = Stop **NENO**
2. Do the devices have the same intended use? • Review labeling to assure consistency w/ IFU form and 510(k) Summary. • Note that performance data can occasionally be used to determine if a different indication does or does not create a different intended use.	X		If **YES** = Go to 3 If **NO** = Stop **AINE** or **NENI**

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3. Do the devices have the same technological characteristics? • Note that this question should be interpreted narrowly. • Unless the subject device is practically identical to a predicate, answer 'no' to this question.	X	X	If **YES** = Stop **SESE** If **NO** = Go to 4
4. Do the different technological characteristics raise different S&E questions?		X	If **YES** = Stop **AINE or NENQ** If **NO** = Go to 5a
5a. Are methods available to evaluate the different technological characteristics?	X		If **YES** = continue If **NO** = Stop **NSE**
Are all necessary performance data available for review?	X		If **YES** = Go to If **NO** = Stop **AINN**
5b. Do the data demonstrate substantial equivalence?	X		If **YES** = Stop **SESE** If **NO** = Stop **NENL**

XIV. Deficiencies : (b)(4) [redacted]
(b)(4) [redacted]

No other deficiency in the submission was detected.

XV. Contact History
(b)(4) [redacted]

XVI. Recommendation : SESE
Regulation Number: 21 CFR 878.4810
Regulation Name:
Regulatory Class: Class II
Product Code: OAP

Digital Signature Concurrence Table	
Reviewer Sign-Off	Sankar P. Basu -S Digitally signed by Sankar P. Basu -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sankar P. Basu -S, 0.9.2342.19200300.100.1.1=1300054169 Date: 2016.01.15 13:49:09 -05'00'
Branch Chief Sign-Off	
Division Sign-Off	

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2017-2470; Released by CDRH on 08-28-2018.

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER K 153618

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed.**

   This change was for reducing the number of LED lamps in the device from 272 to 202.

   _____.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device: **including, labeling, intended use, physical characteristics, and performance are similar except the efficacy in hair growth is slightly less than the unmodified device because the number of lamps being less. No concern about safety of the device exists.**
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

Comments

_____None._____

_____

_____

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	Yes	No	
(Identify the new device and the predicate device) 1. Is the predicate device legally marketed?	X		If **YES** = Go To 2 If **NO** = Stop **NSE**
(Review all labeling and assure that it is consistent with IFU statements) 2. Do the devices have the same intended use?	X		If **YES** = Go to 3, Respond to "A." below If **NO** = Stop **NSE**, Respond to "A." below
(Review design, materials, energy source and other features of the devices) 3. Do the devices have the same technological characteristics?		X	If **YES** = Stop **SE** If **NO** = Go to 4, Respond to "B." below
(Determine what questions of safety and effectiveness the different technological characteristics raise) 4. Do the different technological characteristics of the devices raise different questions of safety and effectiveness?		X	If **YES** = Stop **NSE**, Respond to "C." below If **NO** = Go to 5
(Review the proposed scientific methods for evaluating new/ different characteristics' effects on safety and effectiveness) 5a. Are the methods acceptable?	X		If **YES** = Go to 5b If **NO** = Stop NSE, Respond to "D." below
(Evaluate performance data) 5b. Do the data demonstrate substantial equivalence?	X		If **YES** = Stop **SE,** Respond to "E." below If **NO** = Stop NSE, Respond to "E." below

Note: Please complete the following table and answer the corresponding questions.

A. Please explain how the intended use of the subject device is similar to or different from the predicate device. : **Hair Growth in female population remains the same in the modified device as was in the predicate unmodified device.**

B. Please describe the different technological characteristics.

C. Please explain how the technological characteristics raise different questions of safety and effectiveness

D. Please explain why the proposed scientific method for evaluating new/ different characteristics' effects on safety and effectiveness are not acceptable.

E. Please explain how the data do or do not demonstrate substantial equivalence.

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Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off (optional)	
Division Sign-Off (optional)	

Revised: 8/1/03
10/16/2012 – MMJ placed in Digital Signature format
1/28/13; GKP: Division digital signature optional
2/7/2013 – MMJ: BC signature optional. Per Barb's latest update (2/6/13), review memos and checklists only need to be digitally signed by the reviewer. No other signatures are required. The logging out of a document in CTS and, when applicable, the signing of the letter, is considered an appropriate and sufficient indicator that the review memo or checklist was reviewed by each level of management.
6/5/14: ERJ removed Sections 5c and 6 per Patrick Axtell
9/9/14:FXR replaced the SE decision table to be aligned with the new 510(k) guidance document
9/18/2014: FXR revised the SE decision table, question #4.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118