June 22, 2018

Feilo Sylvania Germany GmbH
% Steve Mlcoch
President
NATS Corp.
PO Box 1257
30 Northport Rd.
Sound Beach, New York 11789

Re: K180581
Trade/Device Name: UV Lamps for Sunlamp Products
Regulation Number: 21 CFR 878.4635
Regulation Name: Ultraviolet Lamp For Tanning
Regulatory Class: Class II
Product Code: LEJ
Dated: February 1, 2018
Received: March 1, 2018

Dear Steve Mlcoch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180581

Device Name
UV Lamps for Sunlamp Products

Indications for Use *(Describe)*
This ultraviolet lamp is intended for use in sunlamp products for tanning of human skin.

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."

510(K) SUMMARY K180581
February 1, 2018

SUBMITTER INFORMATION:

Feilo Sylvania Germany GmbH
Graf-Zeppelin-Str. 9
91056 Erlangen
Germany

Contact: Achim Tonat Email:achim.tonat@feilosylvania

Tel: 49-9131-793-242

APPLICANT/FDA AGENT/CORRESPONDING OFFICIAL INFORMATION:

North American Technical Services (NATS) Corp.
PO Box 1257
Sound Beach, NY 11789
Email: natscorp@aol.com
Contact: Stephen T. Mlcoch

DEVICE NAME:

Common Name: Ultraviolet Sunlamps
Proprietary Model: Component UV Sunlamp Model and Part Number Family per attachment page list

Classification: II
Classification Code, Category: LEJ, 21CFR 878.4635, General & Plastic Surgery

DESCRIPTION:

The component ultraviolet lamp model family or part numbers are for use in sunlamp products to tan human skin. They fall into a generic class of UV lamps that have the same basic technological features, characteristics, except for power rating, diameter and length, with the exact same intended use. The UV sunlamp model family are for tanning human skin use. They vary in brand ID and unique lamp ratings accordingly. These sunlamps fit into a wavelength range of 200-710nm and operate from the end product ballast supply.

There are individual component sunlamps listed in the exhibit page. They are classified as low pressure, mercury rare gas discharge devices and generally have the same construction and technical principals of operation as that of a common fluorescent lamp. The UV lamps have a tubular glass envelope with internal surface coated with fluorescent phosphor. The sealed lamps include the composition and electrical means to activate the UV light within the wavelength specification. The construction is controlled by production procedures and test methods defined in the QMS. The UV radiation is controlled by these methods to assure safe use.

INTENDED USE:

The ultraviolet lamp is intended for use in sunlamp products for tanning human skin.

PREDICATE DEVICES:

Many of the UV sunlamps listed in this 510K previously existed and were offered for sale as class I, 510K exempt medical devices before September 2, 2014. Feilo Sylvania has merged and taken ownership of the Havells Sylvania Germany factory and business including product CDRH submissions by SLI Lichtsysteme GmbH. The model part numbers and brand names added all sustain equivalent construction, characteristics and safe performance. Essentially the newest UV lamps are identical to the sunlamps made at the same location controlled by Havells and substantially equivalent to the other predicate devices cited. All sunlamps listed, now controlled by Feilo Sylvania Germany, have the same intended use, sustain the same technological characteristics and are validated as safe and effective using the control methods and standards testing applied to the designed construction and production.

The predicate devices identified are:

1. Havells Sylvania Germany/ SLI Lichtsysteme GmbH - These companies produced class I 510K exempt UV sunlamps prior to September 2, 2014 of constructions now owned and controlled by Feilo Sylvania Germany at the same Havells location in Erlangen, Germany
2. Kl52273 Cosmedico Light, Inc., dated October 30, 2015
3. K151370 Light Sources Incorporated dated December 17, 2015

The listed UV sunlamps devices made by Feilo Sylvania at the previously owned Havells location, have the same control methods and compliance validation. Brand names added, with part number identifications, have the same technological features and intended use. Cosmedico Light and Light Sources have equivalent over the counter UV sunlamps with the same indications of use. Generally, the constructions are equivalent and are validated as safe and effective.

The fundamental comparison information about critical feature to the predicate devices cited are:

FEATURE /	FEILO SYLVANIA	/ HAYELLS, SLI	/ COSMEDICO	/ LIGHT SOURCES
Factory:	Erlangen Germany	/ Erlangen Germany / Cosmedico	/ Light Sources	
Code/K	LEJ, K180581	/ LEJ 9-2-14 exempt	/ LEJ, K152273	/ LEJ, K151370
Indication:	UV light to tan skin	/ UV light to tan skin	/UV light to tan skin	/ UV light to tan skin
Biocompatibility:	no contact	/ no contact	/ no contact	/ no contact
Power Source	Ballast	/ Ballast	/ Ballast	/ Ballast
Tech Specs:	wavelength* UVA, UVB Florescent	/ same specs*	/ equivalent* Florescent	/ equivalent*
Radiation	21CFR1040.20	/ Accession #s	/CDRH compliant	/CDRH compliant
	Havells, SLI records	0720172-00		
	F Sylvania	1810251-00		

*The standard visual range of fluorescent lamps is 380nm-760nm. The UV radiation range is 300nm – 400nm. These lamps emit their energy closest to the visible range; UVA range 320nm – 400nm, with the emission spectrum range of 260nm – 320nm containing a relative amount of UVB radiation. Feilo Sylvania and all predicate companies comply to the same consensus and industry standards and have equivalent QMS control activity.

PERFORMANCE DATA AND DESIGN CONTROL ACTNITIES:

The Feilo Sylvania UV lamps are intended for use in sunlamp products for tanning of human skin comply with the consensus standards and specifications listed below and are therefore validated as safe for the intended use. The device sunlamps are tested, validated and verification procedures are in place to confirm design specifications. Compliance with the following mandatory and voluntary standards is a QMS requirement:

INTERNATIONAL CONSENSUS STANDARDS AND APPLIED SPECIFICATIONS:

- IEC/EN 61195:2014 - Double Capped Florescent Lamps Safety Specifications
- IEC/EN 60355-2-27:2013 – Particular Appliances Safety Requirements for Skin Exposure to UV and IR Radiation
- EN60081:1998 - Double Capped Fluorescent Lamps - Performance Specifications
- EN61228:2008 - Fluorescent Ultraviolet Lamps Used for Tanning. Measurement and Specification Method
- EN62471:2008- Photobiological Safety of Lamps and Lamp Systems
- EN50581: 2012 - Technical Documentation for the Assessment of Electrical and Electronic with Respect to the Restriction of Hazardous Substances

FDA PERFORMANCE REFERENCE SPECIFICATION:

- 21CFR 1040.20 - Performance standard for sunlamp products and ultraviolet lamps intended for the use in sunlamp products

  Specific performance testing (spectral analysis) data is submitted to CDRH for the component UV lamps with measurement of irradiance to verify compliance with radiation limits defined in 21CFR1040.20.

QUALITY MANAGEMENT SYSTEM COMPLIANCE:

- ISO9001 Quality Management System

Accordingly, factory procedures are established for production, assembly and testing. The control activity shows that there are no new questions of safety and effectiveness for the described UV Sunlamps. The design analysis and predicate comparison confirm the functional characteristics are the same to the predicate devices and raise no other safety or effectiveness issues. Inspection verification procedures assure performance concerns are compliant to QMS specifications.

CONCLUSION:

The Feilo Sylvania UV lamp is intended for use in sunlamp products for tanning of human skin. Each are the same or substantially equivalent to the predicate device sunlamps. They have the same intended use. Havells had FDA/CDRH registration# 1000553841 and SLI had registration #1000533299. They also have a history of UV reporting acknowledged by many related Accession #s that are now part of the Feilo Sylvania compliance records and data. The key comparisons and analysis of the safety, indications, specific use, performance, design, construction, material or chemical composition, energy source, power output, technological prope1ties, skin tan treatments, compliance testing, previous production history and method of operation, the manufacturer Feilo Sylvania verified that no significant differences exist between these device sunlamps and the predicated devices listed. Therefore, substantial equivalence exists.