510(K) SUMMARY
SILK'N INFINITY
510(k) Number K171433

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Trade Name: Silk'n Infinity

Classification Name: 2 1 CFR Classification sections 878.4810 and 882.5890; Product codes OHT, ONF and NFO.

Classification: Class II Medical Device

Predicate Device

The Silk'n Infinity device is substantially equivalent to the previously cleared Silk'n Glide device (Main predicate), also manufactured by the applicant (HomeSkinovations Ltd.). In addition, the Facial Spa device is used as a reference predicate.

Manufacturer	Device	510(k) No.
Home Skinovations Ltd.	Silk'n Glide	K141242
Nu Skin Enterprises Inc.	Facial SPA	K122711

Device Description

The Silk'n Infinity device is designed as a hand held, home use device, which utilizes Intense Pulsed Light (IPL) for hair removal and galvanic microcurrents for skin stimulation. The device comprises a power adaptor and device applicator. The applicator

consists of a single lamp producing the light energy that is emitted via the flash window, and a chrome-coting stripe (touch electrode) located around the flash window, through which the micro-current pulses are discharged. The applicator spot size is 2.7cm$^{2.}$ The user interface located on the applicator contains ON/OFF button, pulsed trigger button and six green LED indicators which provide information on the energy level, system status & errors. The Silk'n Infinity device contains a skin sensor, providing the user with an additional safety measure to detect appropriate skin tones and a proximity sensor that identifies full contact with the skin before pulse activation. The light output power range is from 3 to 5 J/cm ^{2}, the optical filter cut off wavelength is 475-1200nm.

Device Specifications:

Intense Pulsed Light (IPL)	
Light Output Power	3 – 5 J/cm^2
Pulse duration:	500 – 800 µsec
Wavelength:	475-1200nm
Galvanic current pulse parameters (R Load: 500 Ω & 1k Ω.)	
Maximal output current	420 µA
Maximal output voltage	210 mv & 840 mv

Intended Use/Indication for Use

The Silk’n Infinity is an over the counter device intended for the removal of unwanted hair. The Infinity device is also intended for permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

The Silk’n Infinity electric output is indicated for facial stimulation for over-the-counter aesthetic use.

Performance Standards

The Silk'n Infinity device has been tested and complies with the following voluntary recognized standards:

- IEC 60601-1:2012, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

- IEC 60601-1-2 (2014): Medical Electrical Equipment-Part 1: General requirements for safety and Part 1-2 Collateral standard: Electromagnetic Compatibility-Requirements and tests
- IEC 60601-2-57 (2011), Medical Electrical Equipment - Part 2-57: Particular Requirements For The Basic Safety And Essential Performance Of Non-Laser Light Source Equipment Intended For Therapeutic, Diagnostic, Monitoring And Cosmetic/Aesthetic Use.
- IEC 60601-1-11:2010, Medical electrical equipment - Part 1-11: Requirements for the medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 60601-2-10:2012, Medical Electrical Equipment - Part 2-10: Particular Requirements For The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators

Non-Clinical (Bench) Performance Data

The Silk'n Infinity device, IPL optical output performance specifications are based on the same performance specifications as those of the main predicate, the Silk'n Glide which were already evaluated and well established in K131870 & K141242.

Two additional bench tests were performed utilizing the Silk'n Infinity device; the first was evaluating the output performance specifications of the added microcurrent technology. The test results demonstrated that the output parameters complied with the device design requirements and were in line with the reference predicate output specifications.

The second bench test was evaluating the device safety in simulated home use settings, utilizing the device on eight human volunteers while covering five different body areas. The test results showed that the device was safe for use as intended.

Furthermore, the Silk'n Infinity device underwent software validation testing as well as was tested and found to comply with the Electrical and mechanical safety standard

(IEC 60601-1), the electromagnetic compatibility standard (IEC 60601-1-2), the non-laser light source equipment standard (IEC 60601-2-57), requirements for the medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11) and particular requirements for the basic safety and essential performance of nerve and muscle stimulators (IEC 60601-2-10).

The results of the tests demonstrated that all of the device specifications met the system requirements and do not raise new safety or effectiveness concerns.

Animal Performance Data / Histology Data

Not Applicable

Clinical Performance Data

Not Applicable

Substantial Equivalence

The Silk'n Infinity device is basically a modified and upgraded version of the main predicate Silk'n Glide device (510(k) K141242). Both devices utilize optical energy with the same pulse duration, wavelength and light output power. They are both powered on Continuous Operation. The Silk'n Infinity device has similar design, user interface and hardware components as the predicate Silk'n Glide device, with one major modification. The main reason for the submission of this 510(k) application is the addition of the galvanic microcurrents treatment step prior to the existing optical hair removal treatment step in order to add additional feature of skin stimulation to the current indication of hair reduction, while maintaining its safety and effectiveness.

The specifications of the microcurrent technology that is included in the Silk’n Infinity device are identical or in range to that of the Facial Spa device (510(k) K122711), the reference predicate device, a home use non-invasive device intended for facial skin stimulation. Microcurrent technology is a widely used technique in the home use cosmetic applications for skin stimulation. It produces an electrical current that stimulates the skin and increase local blood circulation.

The safety features and compliance with safety standards of the Silk'n Infinity device are similar to the safety features and compliance with safety standards of the predicate devices. All patient contacting materials were tested for biocompatibility and found to

comply with the ISO 10993-1 standard (see detailed biocompatibility testing in Section 15). Furthermore, the design and development phases of the Silk'n Infinity device were composed of a set of performance tests, including software validation testing (provided in Section 16), electrical and mechanical safety testing according to IEC 60601-1 standard, electromagnetic compatibility testing according to IEC 60601-1-2 standard, non-laser light source equipment testing according to IEC 60601-2-57 standard, medical electrical equipment testing in home use environment according to IEC 60601-1-11 standard and particular requirements for the basic safety and essential performance of nerve and muscle stimulators according to IEC 60601-2-10 standard (provided in Section 17) & performance bench tests (provided in Section 18). These performance tests demonstrated that the device specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the Silk'n Infinity device is substantially equivalent to the main predicate Silk'n Glide device (cleared under 510(k) K141242) and to the reference predicate Facial Spa device (cleared under 510(k) K122711 and therefore, may be legally marketed in the USA.