Submitted & Published May 06, 2019.

Device Identifier (DI) Record Details

Sensitive Information

DEVICE INFORMATION

Device Identifier (DI) Information

Issuing Agency: GS1

Primary DI Number: 17290017992003

Device Count: 1

Unit of Use DI Number:

Labeler DUNS Number: 514891048

Company Name: HOME SKINOVATIONS LTD

Company Physical Address: PO BOX 533, UPPER YOKNEAM 2069200 IS

Brand Name: Solio

Version or Model Number: Solio Alfa +

Catalog Number: 7290017992006

Device Description (max 2000 characters):

An over the counter, hand held device, intended to emit energy in the visible, near IR, and RF spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscular and joint pain and stiffness, minor arthritis pain or muscle spasm, the temporary increase in local blood circulation, and temporary relaxation of muscles.

Commercial Distribution

DI Record Publish Date (yyyy-mm-dd): 2019-05-06

Commercial Distribution End Date (yyyy-mm-dd):

Commercial Distribution Status: In Commercial Distribution

Alternative and Additional Identifiers

Direct Marking (DM)

Device Subject to Direct Marking (DM), but Exempt: No

DM DI Different from Primary DI: Yes

DM DI Number: 07290017992006

Secondary DI test

Issuing Agency	Secondary DI Number
No secondary device identifiers currently defined	

Previous DI

Issuing Agency	Previous DI Number
No previous device identifiers currently defined	

Package DI

Package DI Number	Quantity per Package	Contains DI Package	Package Type	Package Discontinue Date	Package Status
27290017992000	1	17290017992003			In Commercial Distribution

Customer Contact

Customer Contact Email	Customer Contact Phone
contact@silkn.com	1-877-367-4556

DEVICE STATUS

Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P): No **Kit:** No **Combination Product:** No

Premarket

Device Exempt from Premarket Submission: No

FDA Premarket Submission Number	Supplement Number	Public Release
K152087	000	Yes

FDA Product Code

Product Code	Product Code Name
ILY	Lamp, Infrared, Therapeutic Heating
GEI	Electrosurgical, Cutting & Coagulation & Accessories

FDA Listing

FDA Listing Number
D271199

GMDN

Code	Name
HCCD	Medium-wave diathermy treatment system generator

DEVICE CHARACTERISTICS

For Single-Use: No

Production Identifier(s) in UDI

Lot or Batch Number:	No
Serial Number:	Yes
Expiration Date:	No
Manufacturing Date:	Yes
Donation Identification Number:	No

Latex Information

Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437): No

Device labeled as "Not made with natural rubber latex": No

Prescription Status

Prescription Use (Rx): No

Over the Counter (OTC): Yes

MRI Safety

What MRI safety information does the labeling contain?: Labeling does not contain MRI Safety Information

Clinically Relevant Size

Size Type Text
No clinically relevant sizes currently defined

Storage and Handling

Storage and Handling
Handling Environment Temperature: between 10 and 35 Degrees Celsius
Storage Environment Temperature: between -40 and 70 Degrees Celsius
Handling Environment Humidity: between 30 and 75 Percent (%) Relative Humidity
Storage Environment Humidity: between 10 and 90 Percent (%) Relative Humidity
Handling Environment Atmospheric Pressure: between 70 and 106 KiloPascal
Storage Environment Atmospheric Pressure: between 50 and 106 KiloPascal

Sterilization

Device Packaged as Sterile: No
Requires Sterilization Prior to Use: No

Sterilization Method
No sterilization method currently defined