K062736

SEP 14 2007

510(k) Summary

September 6, 2007

Company Name & Address: Astron Clinica Ltd
The Mount Toft
Cambridge, United Kingdon
CB3 7RL

Contact Name: E.J. Smith
1676 Village Green, Suite A
Crofton, MD 21114
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Date Summary Prepared: August 31, 2006

Device Identification:

Classification Name:	Light, Surgical, Floor Standing
Common/Usual Name:	Skin Analysis System
Proprietary Name:	SIAscope
Establishment Registration Number:	3004519907
Regulation Number:	21 CFR 878.4580
Product Code:	FSS
Classification Panel:	General & Plastic Surgery
Device Classification:	Class II

Intended Use

The SIAscope is a non-invasive skin analysis system, which provides color bitmaps called 'SIAscans' that show the relative location of blood, collagen and pigment.

CAUTION : This device should only be used to scan the patient's skin.

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Device Overview

The SIAscope is a quick, non-invasive device for imaging skin conditions. It uses a technique known as 'Spectrophotometric Intracutaneous Analysis' (SIAscopy) to identify and display graphically the separate components of the skin. SIAscopy uses a digital camera and light (both visible and near-infrared) to investigate the skin's interior structure.

The SIAscope operates by illuminating the skin with LEDs and measuring the intensity of remitted light. The intensity of the illumination is similar to the emission from a typical hand held torch or remote control unit.

Description of SIAscans

Unlike biopsy, SIAscopy provides an array of readings of the skin that are displayed in graphical form creating a synthesized image called a SIAscan.

Predicate Product Comparison

The SIAscope V operates in a very similar fashion to the predicate device. Where alterations have been make this have been design to improve the imaging performance, reliability and safety of the device over and above the predicate device.

Although the design of the user interface has changed, these changes have been made to make the device easier and more intuitive to use for the clinical practitioner. However, the software algorithms and theory of SIAscopy is the same as found in the predicate device.

We assert that the SIAscope V substantially equivalent to the SIAscope II (K023729)

Summary comparison of features and specification SIAscope V vs. SIAscope II

Parameter	SIAscope V	SIAscope II (K023729)
Product Code	FSS	FSS
Intended Use	SIAscope is a non-invasive skin analysis system, which provides color bitmaps called 'SIAscans' that show the relative location of blood, collagen and pigment.	SIAscope is a non-invasive skin analysis system, which provides a synthesized 'image' showing the relative location of blood, collagen and pigment.
Illumination For:	Skin	Skin
Illumination:	LED	LED
Imager Chip:	CMOS	CCD

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Power Source:	USB via PC	AC
External Materials: (Caseworks)	Glass, ABS & TPE Plastics	Glass, Aluminium
PC Connection:	USB 2.0	Proprietary Umbilical Cable
Weight:	250grams	1Kg
Calibration Method:	Factory Calibrated	Factory Calibrated
Viewfinder:	Colour (3.2 MegaPixel)	Monochrome (0.7 MegaPixel)
Software:	DERMETRICS™ - New User Interface - SIAscopy algorithms unchanged	SIAscope II

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2007

Astron Clinica Limited
% Smith Associates
Mr. E.J. Smith
1676 Village Green, Suite A
Crofton, Maryland 21114

Re: K062736
Trade/Device Name: SIAscope V
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FSS
Dated: June 15, 2007
Received: June 18, 2007

Dear Mr. Smith:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062736

Device Name: SIAscope V

Indications for Use:

The SIAscope is a non-invasive skin analysis system, which provides color bitmaps called 'SIAscans' that show the relative location of blood, collagen and pigment'.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062736