



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

March 10, 2017

Astron Clinica Limited  
c/o 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: PSN  
Dated: June 15, 2007  
Received: June 18, 2007

Dear Mr. Smith:

This letter corrects our substantially equivalent letter of September 14, 2007.

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.

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" (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 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

## 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)

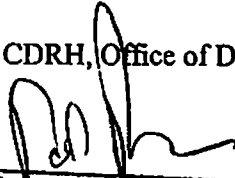
AND/OR

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

Page   1   of   1  

510(k) Number \_\_\_\_\_

  K062736

k062736

SEP 14 2007

## 510(k) Summary

September 6, 2007

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

Contact Name: E.J. Smith  
1676 Village Green, Suite A  
Crofton, MD 21114  
Phone: 888-729-9674  
Fax: 410-793-0448  
Email: [ESmith9746@aol.com](mailto:ESmith9746@aol.com)

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.

K062736

## 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 made this has 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

K062736

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