

510(K) SUMMARY

Agfa Skintell – Optical Coherence Tomography (OCT) System

Common Name: Optical Coherence Tomography (OCT) System
Classification Name: System, Imaging, Optical Coherence Tomography (OCT)
Regulatory Classification: 21 CFR 892.1560
Product Code: NQQ
Proprietary Name: Skintell
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Koen Vervoort, Prepared: September 6, 2013
Telephone: +32-34444-7368

A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa’s Skintell which is an optical coherence tomography (OCT) imaging device. It is substantially equivalent to the system with Michelson Diagnostics VivoSight Topical OCT System (K093520).

B. DEVICE DESCRIPTION

Agfa’s Skintell is an optical coherence tomography imaging device (OCT) weighing approximately 105kg. It is used to create images of non-open wounded human skin and the corresponding close-to-surface tissue.

Skintell offers users the following functions:

- volume and cross-sectional imaging
- high resolution rendering of structures
- geometrical length- measurements

C. INTENDED USE

Agfa’s Skintell is an Optical Coherence Tomography (OCT) system indicated for use in two-dimensional, cross-sectional, real-time imaging of external tissues of human body.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa’s Skintell has an Indications For Use statement identical to the statement for the predicate device, K093520. Intended uses are the same. The devices have the same technological characteristics. Descriptive characteristics and performance data are adequate to ensure equivalence.

Differences in devices do not alter the intended therapeutic/diagnostic effect.

PRODUCT COMPARISON TABLE		
	Skintell (New Device)	Michelson VivoSight Topical OCT (PREDICATE-K093520)
Network Connectivity	Same as predicate	Ethernet
Scanning Technology	Same as predicate	Ultrasound, Near Infra-Red (NIR) Light
Laser Center Wavelength	Same as predicate	1300 nm
Optical Resolution	3 μ m lateral and axial	< 7.5 μ m lateral, < 5 μ m axial
Lateral Scanning Range	1.8mm x 1.5mm (enface)	5mm x 5mm
Image Acquisition Speed	1 fps – Slice (1.8 mm x 1mm) 5 fps – Enface (1.8mm x 1.5mm) 3D – 1.8mm x 1.5mm x 1mm	> 6 fps (5 mm scan width / 1.250 A-line) > 20 fps (1 mm scan width / 250 A-line) > 35 fps (0.2 mm scan width / 50 A-line)
Image Depth	Up to 1.0mm	Up to 2.0 mm
Power Supply	115-120/230V 50-60 Hz	110-132 V 50-60 Hz
Weight	Same as predicate	105 kg
Image Presentation	Same as predicate	Vertical B Scan, En-face, 3D
Image Formats	Same as predicate	DICOM and TIFF Stack
Operating System	Windows XP	Windows 7
Display System	Same as predicate	Standard PC display or separately cleared medical display

E. TECHNOLOGICAL CHARACTERISTICS

Agfa's Skintell is an optical coherence tomography (OCT) imaging device. Principles of operation and technological characteristics of the new and predicate device are largely the same as other optical coherence tomography systems.

The Agfa Skintell system is identical to the Michelson Diagnostic VivoSight Topical OCT system (K093520) with the exception of the following:

- Optical resolution of 3 μ m lateral and axial
- Scanning range of 1.8 mm x 1.5 mm (enface)
- Image depth of up to 1.0 mm

The differences of the devices are optical resolution of < 7.5 μ m for lateral and < 5 μ m for axial of the Michelson Topical OCT device (K093520) is worse with respect to the resolution 3 μ m for both lateral and axial of the Agfa Skintell device. However, the penetration depth of the Michelson Topical OCT device (K093520) is about twice of the penetration depth of the Agfa Skintell device. Even though the Michelson device is able to scan images at a deeper depth, the depth resolution declines while the Agfa Skintell images are clearly separable. Therefore, Agfa's Skintell device produces sharper and clearer images than the Michelson device even

though they are acquired at a shallower depth. Furthermore, this depth of 1.0mm in the epidermal / dermal junction in most cases is where many of the significant changes/structures/lesions are present. The Michelson Topical OCT device (K093520) allows for a wider scanning range of 5mm x 5mm than the Agfa Skintell device which is 1.8mm x 1.5mm (enface). However, the Skintell probe is movable allowing the smaller field of view (scanning range) to be moved to the required section where all the area can be viewed. However, these differences are minor and would not be expected to impact safety and effectiveness.

F. TESTING

The device has completed verification and validation testing to confirm it meets specifications and operates as planned. Tests included standard workflow tests, biocompatibility tests, and image quality evaluations with external and internal experts comparing Agfa's Skintell device to the Michelson Diagnostics VivoSight Topical OCT (K093520) predicate device.

Images were taken using both the slice and enface modes of the Skintell device and analysed histopathologically. Typical patterns of normal skin as well as typical patterns of lesions itself visible on the standard HE stained histopathology section can be linked to image patterns visible in the slice- and enface-images of the Skintell device. Thus, Skintell offers the possibility to visualize skin-structures in-vivo.

The product, manufacturing and development processes have been shown to conform to product safety, radiology, and imaging standards including:

PRODUCT STANDARDS

- IEC 60601-1: 2005 Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1-2: 2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- EN 1041:2008 Information Supplied by the Manufacturers of Medical Devices

QUALITY MANAGEMENT STANDARDS

- ISO 14971:2007 Application of Risk Management to Medical Devices
- ISO 13485:2003 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes
- ISO 10993-1:2009 – Biocompatibility Evaluation and Testing within Risk Management Process
- ISO10993-5: 2009 - Biocompatibility: Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity
- ISO10993-10: 2010 - Biocompatibility: Tests for Irritation and Skin Sensitation
- ISO10993-12: 2007 - Biocompatibility: Sample Preparation and Reference Materials

NOTE: Agfa recognizes two other standards (AOL 2008 and IEC60601-2-37) associated with

the product classification NQQ; however, Agfa does not feel these standards apply to Skintell and Michelson's VivoSight devices. Please refer to **Exhibit 8** for the explanation of this determination.

G. CONCLUSIONS

Agfa's Skintell device has an Indications For Use statement that is identical to the statement for the predicate device, K093520. Intended uses are the same.

Agfa's Skintell system is substantially equivalent to Michelson Diagnostic's VivoSight Topical OCT System (K093520) in that it uses the same technology to create images of non-open wounded human skin and the corresponding close-to-surface tissue. Both Agfa's Skintell device and Michelson Diagnostics VivoSight Topical OCT device (K093520) use the same components including, a non-invasive probe, PC with monitor, and foot pedal. Both the new device and the predicate device weigh 105kg and use a comparable Windows operating system. Agfa's Skintell system and Michelson Diagnostic's VivoSight Topical OCT system (K093520) both offer volume and cross-sectional imaging, high resolution, and geometric length measurements.

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.



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

March 3, 2014

Agfa HealthCare N.V.
% Ms. ShaeAnn Cavanagh
AGFA Healthcare
10 South Academy Street
Greenville, South Carolina 29601

Re: K132800

Trade/Device Name: Agfa Healthcare N.V Skintell
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: NQQ
Dated: January 17, 2014
Received: January 22, 2014

Dear Ms. Cavanagh:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Felipe Aguel

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

Enclosure

Indications for Use

510(k) Number (if known)

k132800

Device Name

Agfa Healthcare N.V Skintell

Indications for Use (Describe)

Agfa's Skintell is an Optical Coherence Tomography (OCT) system indicated for use in two-dimensional, cross-sectional, real-time imaging of external tissues of human body.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Felipe Aguel Date: 2014.03.03
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