Section 6: 510(k) Summary

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Proprietary Name: VivaScope® System

Common Name: In vivo confocal reflectance microscope

Classification Name: Surgical Lamp (21 CFR 878.4580, Product Code PSN)

510(k) Number and Product Code of Predicate Device

VivaScope® System
510(k) Number: K080788
Product Code: PSN
CFR Section: 878.4580

Intended Use/Indication for Use

The modified VivaScope® System has the same intended use as the previously cleared VivaScope System, *i.e.*, it is an in vivo confocal reflectance microscope that uses reflected light to capture images of the skin. The modified VivaScope System has the following Indication for Use:

> The VivaScope® System is intended to acquire, store, retrieve, display and transfer in vivo images of tissue, including blood, collagen and pigment, in exposed unstained epithelium and the supporting stroma for review by physicians to assist in forming a clinical judgment.

Device Description

The VivaScope® System is a reflectance confocal microscope, full color macroscopic imager, and software that captures images of in vivo tissue specimens from the exposed surface of the tissue, through the unstained epithelium and into the superficial supporting stroma. It provides

non-invasive in vivo images of the epithelium and supporting stroma. The VivaScope® System does **NOT** provide automated analysis or diagnosis of the images it produces. It is capable of imaging cells in the epidermis of skin and the fibrous tissue (primarily collagen and fibrin) in the dermis. In addition, it is possible to visualize circulation of blood cells (including both erythrocytes and leukocytes) in capillaries and other small vessels.

The VivaScope® System produces horizontal sections of the skin using safe, low power infrared laser light at nominal wavelength of 830 nm (CDRH laser Class 1). Horizontal sections make it straightforward to view the various layers of the skin in sequence, from the outer surface of the stratum corneum, through the granular, spinous and basal layers, to the level of the superficial reticular dermis.

The VivaScope® System produces high resolution images of the skin using confocal laser scanning microscopy. The key feature of confocal microscopy is the ability to produce in-focus images of thick specimens called "optical sectioning". The system is able to accomplish this by having the point source laser light, the illuminated spot in the sample, and the pinhole all lie in optically conjugate focal planes. The size of the pinhole (located in front of the photodiode) is matched to the size of the illuminated spot to reject out of focus light allowing for imaging of thin optical sections.

The VivaScope® System can image, display, store, retrieve, import and export in vivo confocal and macroscopic color images using the VivaScan® operating software and supporting PC hardware. Images are saved and stored using standard lossless image compression algorithms. Images are communicated to other devices using DICOM standard functionality that is incorporated into the VivaScan® operating software.

The VivaScope® System is comprised of four (4) major functional components: an imager, a display, a PC and a cart. A VivaScope® System will have either a VivaScope® arm mounted imaging head or a VivaScope® handheld imaging head, or both, and optionally, a VivaCam® full color macroscopic imaging head.

Technological Characteristics

The modified VivaScope System has the same fundamental scientific technology as the predicate device. The main differences between the modified VivaScope System and the predicate are as follows:

- Display: The predicate device has a LCD display, which is no longer commercially available. The modified VivaScope System has a 23 inch, multi-touch, energy efficient backlit LED display.

- Handheld Imager: The Handheld Imager in the modified device has a different body style; the internal engine and optics in the modified device are the same as in the predicate.

- Medical Grade Cart: The medical grade cart for the modified VivaScope has a different style/design with a vertically mounted computer compartment, different locations for mounts for the Handheld Imager and VivaCam images, and compartments for disposables.

- Arm Mounted Imager: In the modified device, a resonant scanner is used in the Arm Mounted Imager in lieu of a polygon scanner that is used in the predicate's Arm Mounted Imager. This resonant scanner is the same as the resonant scanner that is used in the Handheld Imager in both the modified device and the predicate. The resonant scanner provides the same high-resolution image that is provided by polygon scanner but allows for a smaller, more ergonomic design of the Arm Mounted Imager.

- Tissue Interface: In the modified device, a single-use (disposable), one-piece tissue cap with a "molded-in" polycarbonate window is used with the arm-mounted imaging head. This replaces the stainless steel tissue ring with a disposable polycarbonate window in the predicate.

- Isolation Transformer: IEC 60601-1 Ed. 3.1 published a change to leakage current limits that allows for removal of the isolation transformer in the modified device.

- Windows Compatibility: Windows XP (that is used in the predicate) is no longer supported by Microsoft, Inc. The modified device uses Windows 10 OS (Microsoft, Inc.). Windows 10 OS is the most current operating system provided by Microsoft, and allows for routine updates and patches, installed by the user, to remediate vulnerabilities associated with controlled risk of patient harm.

- Software: The predicate has a frame rate of 9 fps on the arm mounted imager, and 6 fps on the handheld imager; the modified device has a frame rate of 6 fps on both the arm mounted imager and the handheld imager. In addition, the "capture confocal" button on the screen that is used to capture the real-time image currently displayed on the screen was replaced by a camera icon with the same function.

<u>Performance Data</u>

The VivaScope was subjected to verification and safety testing to ensure that it complies with relevant industry and safety standards and conforms to its specifications. Testing of the VivaScope included:

- Electrical Safety was tested according to IEC 60601-1 Ed. 3.1
- EMC/EMI was tested according to IEC 60601-1-2 Ed. 4
- Laser Safety was tested according to IEC 60825-1 Ed. 3

Validation data to confirm the visualization of blood collagen and pigment in the images produced by the VivaScope were submitted for the predicate. No similar data were generated for the modified device because the fundamental scientific technology did not change.

Conclusion

The modified VivaScope® System has the same intended use and fundamental technology as the previously cleared VivaScope System. The minor technological differences between the 510(k)-cleared and the modified devices do not raise new questions of safety and effectiveness, and the modified device is at least as safe and effective as the previously cleared VivaScope System. As a result, the modified VivaScope System described in this submission is substantially equivalent to the predicate device.