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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

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Nevoscope is a hand-held, skin examination microscope that is similar in concept to the Episcopes (k920103) and the Dermatoscope devices approved by the FDA. It is a non invasive device that is designed to view skin lesions by either surface illumination or transillumination. Light is directed onto the skin by a special light ring that is coupled to an AC powered halogen lamp by an optical fiber bundle. Built-in mirrors permit viewing a skin lesion from different elevations and angles simultaneously. A variable focus zoom lens controls the magnification of the lesion and a CCD TV camera is attached for image viewing and digitization. Skin lesion images can be stored in the computer for analysis and archiving.

The Nevoscope can be operated with surface illumination of the skin in a manner similar to the Episcopes and the Dermatoscope. The transillumination modality offers additional information by lighting the skin lesion from scattered light within the skin. The mirror assembly, which provides simultaneous views of the lesion from different angles and elevations, is also a feature of the Nevoscope not found in either the Episcopes or the Dermatoscope. Image capture by a CCD camera and viewing of the image by a TV monitor is available as an option in the Dermatoscope while it is a standard feature in the Nevoscope. The Nevoscope comprises a computer database and patient archival storage as a standard feature.

The Episcopes has been in clinical use since 1992 and has demonstrated its ability to highlight skin lesion features with surface lighting and oil immersion techniques. The Nevoscope has been in clinical research setting for the last three years and has been tested in skin lesion patients. Research papers and scientific presentations have been made that demonstrate the surface illumination imaging with the Nevoscope and the additional information obtained by transillumination. The Nevoscope and the Episcopes are substantially equivalent in their ability to perform surface illumination and

magnification of the skin lesion. However, the Nevoscope has additional features such as transillumination and mirror views not found with either the Episcopes or the Dermatoscope.

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