

# NIDEK INNOVATION

PROVIDING SALES AND SERVICE FOR OPHTHALMIC LASERS, REFRACTIVE LASERS, AND MANY ADVANCED DIAGNOSTIC DEVICES.

*September 6, 2016*

NIDEK, a global leader in laser and diagnostic instrumentation for the eye care industry, is pleased to announce that the United States Food & Drug Administration (FDA) has issued 510 K Clearance for the Manual Analysis Function for the CEM-530 Specular Microscope. With FDA clearance, the manual analysis feature is now available in the USA. This feature will enable practitioners to analyze cells manually that are not identified by the auto-analysis function due to poor image quality.

The CEM-530 Specular Microscope can be upgraded to manual analysis function by a software upgrade. The center point manual analysis is initiated by selecting the approximate center of a cell. Adjoining cells are then detected based on the surrounding points. This method is particularly effective for areas where groups of cells are clumped together. The versatility of automated and manual analysis allows speed and precision.

## About NIDEK:

Founded in Gamagori, Japan in 1971, NIDEK continues to be a global leader in research and development, design, manufacture and distribution of ophthalmic equipment. The United States subsidiary based in Silicon Valley, California, provides sales and service for ophthalmic lasers, refractive lasers, and many advanced diagnostic devices.

Caution: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner. Specifications may vary depending on circumstances in each country. Specifications and design are subject to change without notice.

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