Konan Medical’s EvokeDx®, the Next Generation VEP + ERG Vision Diagnostics Platform, Achieves the CE Mark Including Glaucoma Diagnostic Indication

Robust, User-Friendly and Affordable In-office Visual Pathway Diagnostics Technology Featuring icVEP™ Provides Important Information About the Functional Integrity of the Visual System.

Irvine, California (PRWEB) July 17, 2017 -- Konan Medical (www.KonanMedical.com), a global leader in innovative diagnostic devices for the ophthalmic industry, today announced that it has attained the CE mark for its newest device, EvokeDx. The CE mark is required in Europe by 30 countries in order to market medical devices and is an assurance that the product complies with relevant European health, safety and environment protections. EvokeDx is now approved in Europe for objective assessment of central vision function including the diagnosis of glaucoma.

Visual evoked potentials (VEP) are vision-produced, electrophysiological signals recorded near the brain’s visual cortex used to assess visual function and in the case of EvokeDx, include a rapid and objective assessment of magnocellular deficits often associated with glaucoma. Electroretinogram (ERG) signals are recorded in a similar manner but used to assess retina-specific dysfunctions.

icVEP is the patented, isolated-check VEP stimulus and analysis strategy that was the subject of an NIH-sponsored, multi-center clinical trial at five prestigious US sites and two international locations to rapidly and objectively assess glaucomatous damage. “In the NIH-sponsored trials, our icVEP strategy had a classification accuracy of 89 to 94% for glaucoma,” said Vance Zemon, PhD, a professor at Yeshiva University, Albert Einstein College of Medicine Campus and co-inventor of EvokeDx. “A glaucoma diagnostic indication based upon this data has also been granted for the icVEP strategy in China,” said George Hu, PhD, co-inventor.

EvokeDx will be featured at the European Ophthalmology meeting, the ESCRS in Lisbon in October 2017. “We worked closely with Dr. Zemon’s team to commercialize a visual pathway diagnostic platform for Europe with cutting edge features that is elegantly designed, easy to use, reasonably priced and meets the high technical standards essential for clinical electrophysiology of vision.” said Dr. Charles Wm. Stewart, Chief Executive Officer at Konan Medical USA. “The glaucoma diagnostic indication for EvokeDx in Europe has generated strong interest from the European ophthalmic community with its proprietary icVEP testing strategy.”

EvokeDx features include patented test strategies that are designed to isolate and objectively test various visual pathways and visual functions, with Fourier-transform frequency analysis methods, and an all-in-one design incorporating a state of the art organic LED stimulus display. Proprietary analysis of the entire EEG waveform provides new information about visual pathway function. EvokeDx is also FDA 510(k) cleared in the USA for objective study of central visual function. Low-cost consumables are available from Konan or other suppliers using industry-standard connectors.

About Konan Medical USA, Inc.
Headquartered in Irvine, California, Konan Medical USA Inc. develops specialized diagnostic products for eye care clinicians and eye banks. The company also provides diagnostic equipment and support services to many
of the leading ophthalmic manufactures in support of sponsored FDA clinical trials research globally. For more information visit www.KonanMedical.com.
Contact Information
Ian McMillan
Konan Medical USA, Inc.
http://www.konanmedical.com
+1 (949) 521-7730 Ext: 7743

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