Dec 16, 2019

IMAnalytics and MRIxViP Qualified by FDA for Magnetic Resonance Imaging Safety Evaluations

This is Big: ZMT's IMAnalytics evaluation tool and the IT'IS field libraries MRIxViP1.5T/3.0T become the first FDA-approved computational modeling Medical Device Development Tool (MDDT)

On December 12, 2019 the U.S. Food and Drug Administration (FDA) announced the acceptance of ZMT's Sim4Life IMAnalytics and the field exposure libraries MRIxVIP1.5T and MRIxViP3.0T from the IT'IS Foundation as a Medical Device Development tool (MDDT). This qualification marks a major breakthrough for Z43 in our endeavors to develop reliable and qualified tools for supporting medical device development and treatment planning and improving and ensuring patient safety.

The MDDT label of our software tools certifies that evaluations of the health risks posed by active implantable medical devices (AIMDs) to patients undergoing magnetic resonance imaging (MRI) diagnostics are traceable, easy-to-conduct, and standardized at the most comprehensive level. The combined usage of IMAnalytics and MRIxViP1.5/3.0T guarantees the quality of the MRI safety evaluations and enables the medical device industry to accelerate the approval process with even enhanced quality of the risks evaluation and allows regulators to focus on other safety-relevant aspects of the approval submission.

According to Edward Margerrison, Ph.D., Director, Office of Science and Engineering Laboratories, Center for Devices and Radiological Health (CDRH), FDA, "IMAnalytics with MRIxViP1.5T/3.0T and BCLib Toolset may be used in the premarket submissions of AIMDs to obtain the statistical distribution of the in vivo deposited power and/or induced terminal voltage to support MR Conditional labeling of these medical devices for 1.5T or 3T MR scanners, according to the Tier 3 approach defined in ISO/TS 10974:2018". In other words, applying a qualified MDDT tool as non-clinical assessment model eliminates much of the risk and uncertainty manufacturers often experience in product development. Learn more about the FDA's MDDT program here.

We are happy to answer any further questions you may have. For more formation, contact us at sales@zmt.swiss.

FDA Qualifies MRI Compatibility and Safety Software as a New Medical Device Development Tool

The U.S. Food and Drug Administration (FDA) has qualified the IMAnalytics with MRIxViP1.5T/3.0T And BCLib extraction and evaluation tool through the Medical Device Development Tools (MDDT) program. This is the first computational modeling tool that can be used across a wide range of active implantable medical devices (AIMDs) and manufacturers qualified through the MDDT program.

The IMAnalytics with MRIxViP1.5T/3.0T and BCLib is a method for manufacturers to evaluate safety and compatibility of AIMDs active implanted medical devices in common magnetic resonance imaging (MRI) environments. Medical device sponsors interested in using this tool in device development should review the MDDT Qualification Summary for this tool, which presents a summary of the scientific evidence that served as the basis of the qualification decision.

Read the IMAnalytics Summary

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