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QUOTED. March 22, 2019. Scott Gottlieb.

by

US FDA recently qualified the *OsiriX CDE* Software Module as a Medical Device Development Tool (MDDT), making it the third MDDT qualified by the agency and the first biomarker MDDT. See what FDA Commissioner Scott Gottlieb said about it here.

“Today's qualification of the first biomarker test for brain injury may help innovators more efficiently enroll patients in clinical trials of therapeutic medical devices intended to be used to treat mild traumatic brain injury. A strategic goal of the FDA is to promote the creation and validation of biomarkers and development tools that can provide more efficient and accurate ways to evaluate the safety and effectiveness of products.” –Scott Gottlieb, commissioner, US FDA

- Find out more: *No Brainer: US FDA Greenlights First Biomarker Software As Medical Device Development Tool for Brain Injury*