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iSchemaView Completes MDSAP Audit Moves to Expand Worldwide Adoption of RAPID™ Imaging Platform

Critical International Audit Paves Way for Regulatory Application and Approvals Around the World. Canadian Representative Launched.

Redwood City, Calif. – June 5, 2018 – iSchemaView, the leader in cerebrovascular imaging analysis, today announced that the company has completed the Medical Device Single Audit Program (MDSAP), with coming certification. iSchemaView is now applying for clearances and approvals of the RAPID imaging platform in all participating countries around the world.

In 2014, the International Medical Device Regulators Forum (IMDRF) launched a global approach to auditing and monitoring the manufacturing of medical devices, in an effort to improve safety and oversight on an international scale. The result was the creation of the MDSAP, a regulatory audit that serves as a critical step in satisfying the relevant requirements of international regulatory authorities.

MDSAP participating countries include Australia, Brazil, Canada, Japan and the United States, with the World Health Organization and European Union among official observers.

“With dozens of new stroke centers installing RAPID’s automated CTP, MR, CTA and ASPECTS solutions each month, we are seeing accelerating adoption this year,” said Don Listwin, CEO of iSchemaView. “Now that we have completed the MDSAP we are looking to ensure that patients to our North, and around the world, can take advantage of our unmatched imaging solutions. Our mission is to help health care systems address and treat more stroke patients than ever before, and this news moves us ever more swiftly down the path of success.”

With MDSAP complete, iSchemaview will be pursuing approval for RAPID in all participating countries, with estimated clearance in Canada expected this summer. In lock-step with the process, iSchemaview is also announcing that Kevin Talmage of Yocan Medical Systems will partner with the company as a Canadian region representative. Talmage brings with him over twenty years of successful medical device marketing and sales experience across Canada.

For more information about working with RAPID in Canada, contact Kevin Talmage at (647) 271- 2516 or at kevin.talmage@yocanmedical.ca.

About iSchemaView

iSchemaView is the leader in cerebrovascular imaging analysis, delivering the proven software tools that healthcare professionals around the world use to successfully identify and treat more stroke patients than ever before. Already installed in over 400 hospitals and stroke centers, iSchemaView's RAPID (automated CTP, MR, CTA and ASPECTS), is the most advanced brain imaging platform. In clinical trials, under IRB, RAPID has been shown to aid in the selection of patients in early and late window stroke trials, including SWIFT PRIME, EXTEND IA, DAWN and DEFUSE 3. In addition to achieving the best clinical outcomes and largest treatment effects ever obtained, these landmark studies led to new American Heart Association and American Stroke Association guidelines and have dramatically altered the management of acute stroke around the world. For more information, visit www.iRAPID.com.

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