Mirada Medical receives FDA 510(k) clearance for the world's first Artificial Intelligence (AI) software, DLCExpert™, for automated contouring of critical structures in radiation oncology treatment planning

Oxford, July 18th – Mirada Medical, a leading global brand in medical imaging software, has received FDA 510(k) clearance to market its Deep Learning Contouring (DLC) software, DLCExpert, for clinical use in the USA.

One of the first steps in the radiation therapy treatment planning process requires clinical staff to delineate the tumor and associated critical structures (organs-at-risk) on a CT scan of the patient. This is a time consuming and potentially error prone task.

Mirada's DLCExpert uses Deep Learning, a form of Artificial Intelligence technology, to fully automate this process. By using AI to mimic the best human expert contouring, DLCExpert can automatically generate contours that clinical users often find indistinguishable from human drawn contours. As a consequence, DLCExpert has been shown to save up to 75% of the time required for this task, therefore accelerating the treatment pathway for the patient.

DLCExpert received CE marking for the European market earlier this year and hospitals across Europe are already commissioning the product in order to benefit from exceptional time savings and increased consistency in their contouring workflow. Receipt of FDA clearance now allows radiotherapy sites in the USA to put DLCExpert into daily clinical use.

Andre Dekker, Professor of Clinical Data Science, Department of Radiation Oncology at the Maastro Clinic in Maastricht, The Netherlands, states: "The contours generated by DLCExpert are the closest to clinically acceptable contours we've seen from any autocontouring system we have evaluated. For some organs, our clinicians found it very hard to distinguish between their own contours and those that were automatically generated."

Regulatory approval for DLCExpert was granted as part of the FDA 510(k) clearance for Workflow Box™ 2.0, Mirada's Zero-Click™ automation platform, where it is included as an option along with five additional Zero-Click workflows, including multi-modal autocontouring, routing of data, and support for the integration of custom applications.

Hugh Bettesworth, Chief Executive at Mirada Medical states: "We are delighted to be cleared to offer this breakthrough technology to our US customers. Mirada is proud to be the first company in the world to be marketing AI based solutions to the everyday problems faced by doctors planning radiation treatment for their cancer patients."

About Mirada Medical

Mirada Medical is a leading international brand in medical imaging. The company develops advanced technology applications that help healthcare professionals use medical images more effectively and efficiently to improve cancer care. Mirada's products are used across diagnostic radiology, molecular imaging, radiation oncology, medical oncology, tumor board and elsewhere.
The company specializes in simplifying technically complex image processing tasks, allowing clinicians to more confidently diagnose disease, assess response to treatment, and plan radiation therapy or surgical intervention. Mirada's advanced technology products are available throughout the world under its own brand, and on an OEM basis through a select number of the world's leading healthcare companies.

Mirada Medical, DLCExpert, Workflow Box and Zero-Click Contouring are trademarks of Mirada Medical Ltd.

To learn more about Mirada Medical, please visit: www.mirada-medical.com

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