

C4 Imaging Announces FDA 510(k) Clearance of its Non-metallic, Multimodality C4 Fiducial Marker

HOUSTON, TX, USA, October 26, 2020 /EINPresswire.com/ -- C4 Imaging Announces FDA 510(k) Clearance of its Non-metallic, Multimodality C4 Fiducial Marker

C4 Imaging LLC announces U.S. Food and Drug Administration 510(k) clearance of its third major product, the Multimodality C4 Fiducial Marker. This novel positive-signal MRI marker will be implanted into patients in situations where the location of specific anatomy, normal or diseased, needs to be marked for a future medical procedure. The device can be visualized using MRI, CT or x-ray, and provides a reference from which other procedures can be guided, for example during the treatment of cancer with radiotherapy.

Image guidance utilizing fiducial markers is an important option to reduce margins of uncertainty during radiotherapy treatment planning, and for alignment prior to treatment delivery. This ensures radiation is focused on the cancer, rather than on surrounding healthy anatomy, optimizing cure rates and minimizing the risk of side effects. Most fiducial markers contain a solid metal component which can cause distortions, or artifacts, especially on MR images. These artifacts may compromise image quality of the underlying cancer and surrounding anatomy. The C4 Fiducial Marker contains a proprietary, patented combination of non-metallic materials that allow for a positive-signal with MR, CT, and X-ray imaging.

Radiation Oncologists and their teams often combine MR and CT images, referred to as co-registration or image fusion, to precisely plan where radiotherapy will be targeted. With the C4 Fiducial Marker they will be able to co-register MR and CT images without the concern of image artifacts, and do so throughout the course of a patient's treatment.

"510(k) clearance for our Multimodality C4 Fiducial Marker is another major milestone for C4 Imaging," said Andrew Bright, C4 Imaging's President and CEO. "The approval of this important Radiation Oncology product allows us to offer the benefits of positive-signal MR imaging when treating the hundreds of thousands of patients who receive radiotherapy each year." He added, "With 510(k) clearance we're ready to transfer the device to production and will announce commercial availability to address this significant market in 2021."

C4 Imaging will be discussing plans for launch and availability of the Multimodality C4 Fiducial Marker with the Radiation Oncology community during the ongoing annual American Society for

Radiation Oncology (ASTRO) meeting.

About C4 IMAGING

C4 Imaging develops medical devices that enable clinicians to more accurately perform image-guided procedures. The company's proprietary technology, C4, has been developed as Sirius[®], the first commercially available Positive-Signal MRI Marker, as well as Orion[™], an MRI Marker that enables accurate MRI-based treatment planning for cancer patients being treated with high dose rate (HDR) brachytherapy. Sirius[®] and Orion[™] are enabling the adoption of MARS – MRI-Assisted RadioSurgery. Further information is available at www.c4imaging.com

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