

C4 Imaging Announces FDA 510(k) Clearance of its Positive-Signal High Dose Rate (HDR) Brachytherapy MRI Treatment Planning Marker

Houston, Texas, (May 8, 2018) – C4 Imaging LLC announces U.S. Food and Drug Administration 510(k) clearance of its second major brachytherapy product, the HDR MRI Marker. This novel, Positive-Signal MRI Marker will be used prior to high dose rate (HDR) brachytherapy to accurately locate the position of the applicators that guide the placement of radioactive sources for the treatment of multiple cancers.

High dose rate (HDR) brachytherapy is a form of radiotherapy and a standard option for the curative treatment of many forms of cancer. HDR brachytherapy involves temporarily placing an applicator or needles into the patient and then using medical imaging to identify their location in relation to the cancer and surrounding healthy tissue. A radioactive source is placed inside the applicator and irradiates the immediate vicinity of the cancer before being removed. The popularity of HDR has increased in recent years due to its effectiveness and convenience; and the majority of Radiation Oncology practices in the US are able to offer the technique.

The precise positioning of HDR applicators and needles prior to treatment is critical for accurate delivery of therapy. Currently, placement of applicators is usually guided by computed tomography (CT) imaging of metal wires that are temporarily placed inside the applicator. These metal wires are not reliably imaged with MRI. C4 Imaging's Positive-Signal HDR MRI Marker allows the superior anatomical imaging properties of MRI to be effectively utilized when planning HDR treatment and offers the potential for effective treatment that minimizes the possibility of side effects.

"510(k) clearance for our HDR MRI Marker is another major milestone for C4 Imaging," said Andrew Bright, President and CEO. "The approval of an additional Radiation Oncology product based on the encapsulation of our unique MRI agent allows accurate positive-signal MRI treatment planning to be offered to all cancer patients suitable for HDR treatment." He added, "With 510(k) clearance of this important product we're able to actively transfer the device to production and will announce commercial availability in the near future."

About C4 IMAGING

C4 Imaging LLC develops medical devices that enable clinicians to more accurately perform image-guided procedures. The company's core proprietary technology, C4, has previously been developed as Sirius™, the first commercially available Positive-Signal MRI Marker, and will soon be available as an HDR MRI Marker that aids accurate MRI – based treatment planning for cancer patients being treated with high dose rate (HDR) brachytherapy. Further information is available at www.c4imaging.com

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