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1st Orthopedic De Novo Granted by the FDA to IlluminOss Medical

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MCRA Assists IlluminOss Medical with Successful De Novo Decision: 1st Orthopedic De Novo Granted by the FDA



Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA) has announced its role in the successful granting of the first orthopedic de novo by the U.S. Food and Drug Administration (FDA).

It allows IlluminOss Medical, Inc. to initiate commercialization in the U.S. of the Bone Stabilization System for treatment of impending and actual pathological fractures of the humerus, radius and ulna from metastatic bone disease.

IlluminOss Medical retained MCRA in August of 2016 to lead interactions and correspondence with the FDA for the Bone Stabilization System.

The IlluminOss System is a PET balloon infused with a photodynamic monomer, which when exposed to light, polymerizes the monomer, resulting in a solid intramedullary (IM) rod.

This is an important treatment option for the fixation and stabilization of actual and impending pathological fractures of the humerus through a minimally invasive procedure.