July 15, 2021

NuVasive statement on MAGEC device system

NuVasive Specialized Orthopedics, a subsidiary of NuVasive, has lifted the U.S. voluntary ship hold on the MAGEC device system and the modified MAGEC X device is available for sale, effective immediately. This decision was made after discussions between the U.S. Food and Drug Administration (FDA) and the Company, following a number of interactions over the last several months regarding available biocompatibility testing results, other available data, and the overall risks and benefits of the device.

In noting its potential concerns with the device, the FDA stated:

"On July 15, 2021, NuVasive posted an updated statement informing U.S. health care providers that the ship hold in the U.S. has been lifted for the MAGEC devices. The FDA believes it is in the best interest of patients to make the modified MAGEC X device available in the U.S. at this time because

(1) the overall benefits of the device outweigh the known risks for on-label use in the U.S. compared to alternative treatments,

(2) the U.S. indications and instructions for use, which restrict use to patients less than 10 years old and for a two-year implantation time, further mitigate known risks,

(3) the modified MAGEC X (MAGEC 2b) device, designed to mitigate endcap separation events and related biocompatibility concerns, will be the only device version currently available for sale in the U.S., and

(4) the U.S. labeling has been updated to include a discussion of known risks associated with the device."

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