Exactech®
Surgeon focused. Patient driven.™

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To Whom It May Concern,

Exactech is the distributor of Optecure®, Optecure+CCC®, Entice, Entice+CCC®, and Opteform®. These products are engineered human bone grafts that are regulated in the United States as medical devices and were cleared via 510(k). Previously, these products were required to be registered with the FDA on both the tissue establishment listing and the medical device establishment listing. However, effective January 1st, 2019, the FDA changed its stance.

A recent statement from the FDA says that only establishments that manufacturer human cell tissue and cellular and tissue based products (HCT/Ps) regulated solely "under Section 361 of the Public Health Service (PHS) Act" are required to register and list their HCT/Ps "in Section 361 are products such as pericardium membrane or allograft bone that is minimally manipulated and not combined with another article such as a hydrogel carrier. Currently, Exactech does not supply any of these "tissue only" allograft products. Therefore, Exactech does not currently have any products registered on the Part 1271 tissue establishment listing.

The statement from the FDA further says that manufacturers of "HCT/Ps that are regulated as drugs, devices, and/or biological products under Section 351 of the PHS Act and/or under the Food, Drug, and Cosmetic Act" must register and list their products "in accordance with 21 CFR Part 207 or 807, as applicable". Because Optecure®, Optecure+CCC®, Entice®, Entice+CCC®, and Opteform® are HCT/Ps that are regulated as medical devices, they are now only listed, as required, under Exactech's Part 807 medical device establishment listing.

To learn more about the tissue establishment listing or the medical device establishment listing, it may be helpful to visit the FDA website at www.fda.gov. For more information about Exactech products, please contact Exactech at 352-377-1140.

Kind regards,

Lee Krengel

Lee Krengel
Tissue Bank Director
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