FDA Regulatory Status – Graftech®

Please be advised that Graftech® Structural Allograft products are comprised entirely of donated cortical and/or cancellous human bone tissue that is minimally manipulated. As such, they meet the criteria established by FDA for regulation of these products as HCT/Ps (human cell, tissue, and cellular and tissue-based products) and are therefore regulated by FDA solely under 21 CFR Part 1271 regulations for HCT/Ps, and not as medical devices under medical device regulations. There is no requirement or provision in the HCT/P regulations in 21 CFR Part 1271 for premarket clearance or approval via a 510k or PMA submission for products regulated solely as HCT/Ps. Thus, there is no 510(k) clearance or PMA approval that exists or that is necessary for distribution of the Graftech products in the U.S. The Graftech products are, however, listed on Osteotech’s tissue establishment registration with FDA, in accordance with establishment registration and HCT/P listing requirements in 21 CFR Part 1271.

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