FDA Regulatory Status – Xpanse®

Please be advised that Xpanse® Bone Insert is comprised entirely of demineralized bone matrix (DBM) made from denated human bone tissue and is a minimally manipulated tissue product. As such, it meets the criteria established by FDA for regulation of the product as a HCT/P (human cell, tissue, and cellular and tissue-based products) and is therefore regulated by FDA solely under 21 CFR Part 1271 regulations for HCT/Ps, and not as a medical device 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 510(k) 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 Xpanse product in the U.S. The Xpanse product is, 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.

Christopher Talbot
Sr. Manager, Regulatory Affairs