WRIGHT
FOCUSED EXCELLENCE

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To Whom it May Concern,

Wright Medical Group recently received FDA Premarket Approval (PMA) of AUGMENT® Bone Graft as an alternative to autograft in arthrodesis (fusion) of the ankle and hindfoot. With this approval, foot and ankle surgeons are now able to offer their patients a truly revolutionary bone healing technology. AUGMENT® Bone Graft is a unique regenerative solution that is different from any other biologic option available today.

AUGMENT® Bone Graft is not regulated as a tissue product under 21 CFR 1271, but is rather classified as a combination medical device/drug and has now been approved via PMA P100006 (attached.) AUGMENT® Bone Graft is composed of recombinant human platelet derived growth factor-BB (rhPDGF-BB) and β-Tricalcium Phosphate Granules at a concentration of 0.3mg of recombinant protein per mL of solution (0.9mg per 3cc Kit.) The product should be stored at standard refrigerated conditions for drugs and drug/device combination products (2°-8° C) to preserve protein viability for the labeled shelf life, which is three years from the date of manufacture.

Please feel free to contact me directly with any additional questions that I may answer.

Kind Regards,

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