March 15, 2011

ATTN: Center for Devices and Radiological Health
Orthopedics and Rehabilitation Advisory Panel FDA

RE: Augment Bone Graft Safety and Effectiveness in Hindfoot and Ankle Arthrodesis

Dear Members of the External Advisory Panel, FDA and Distinguished Guests:

Arthrodesis has been a proven staple for orthopaedic surgeons over the last century as a reliable means of providing deformity, arthritic, and instability correction in symptomatic patients. Still today, this intervention remains the gold standard for many such problems. Perhaps the most significant complication of fusion surgery, however, has been the inherent risk of nonunion—an event which inevitably creates a tremendous burden upon patient, physician, and of course the overall healthcare system.

Nonunion rates in foot and ankle surgery are particularly problematic in some of the higher risk populations that commonly present with foot and ankle pathology, such as those with a history of smoking, diabetes, post-traumatic deformity, or obesity. While autogenous bone grafting has always been the foot and ankle surgeon’s standard adjuvant for augmenting bone healing in these individuals and it has enjoyed reasonable success, it is not employable without supplemental surgery and adding potentially significant perioperative risk.

To date, unlike several other subspecialties in orthopaedic surgery, the field of foot and ankle surgery has regrettably lacked widely accepted and/or proven standard alternatives, as well as level I evidence, supporting any other treatment to enhance fusion beyond autogenous bone graft. Currently, therefore, a significant clinical need exists for a consistent recombinant product, supported by level I evidence, which demonstrates reliable enhancement of bone healing and 1) avoids the potential morbidity and pain associated with graft site harvest, 2) lacks the disease transmission and autoimmune risks common to other currently employed alternative interventions, 3) decreases surgical time or resources by being readily available and easily implantable, and 4) is available in effectively limitless amounts as an osteogenic agent.
Based on the overall strength of the data generated from a randomized, controlled, prospective, multicenter study that incorporated numerous radiologic, clinical, functional, and pain outcome measures, and which represents the largest collective North American IDE investigation performed to date in foot and ankle surgery, we believe Augment Bone Graft may well represent a “new generation” product for use in foot and ankle fusion surgery. The data compiled over the past several years from this work are compelling, and, when considering the fact that outcomes instruments were stringently employed to carefully collect results from the perspective of the patient (functional), surgeon (clinical), and blinded radiologist (radiographic and CT based), we are confident that the information is both relevant and conclusive.

To briefly summarize the results, we believe Augment demonstrated equivalence to our gold standard (autograft) based on numerous clinical, radiologic, functional, and safety endpoints, while eliminating the additional surgery and morbidity associated with bone graft harvest. At six months, 14 of 16 of these endpoints were found statistically significant for non-inferiority, and by twelve months, 15 of 16 endpoints were deemed statistically equivalent. In our opinion, Augment also convincingly achieved the primary endpoint of fusion in the study, as defined by ≥ 50% osseous bridging on CT scans.

In conclusion, it is the view of the investigators, based on the strength of the overall data as well as our clinical judgment from collectively treating 414 patients, that Augment has demonstrated equivalent efficacy and an improved safety profile in comparison to our traditional gold standard (autograft) for foot and ankle arthrodesis procedures. This product, if approved, would provide our specialty an equal means of enhancing osseointegration while eliminating the surgical and anaesthetic risk and morbidity associated with bone graft harvest by offering a viable alternative to autograft in our foot and ankle patients who require optimised bone healing to achieve fusion.

Respectfully Submitted,

Augment Investigator Study Group.
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Gregory Berlet, MD

Christopher Bibbo, MD

Bradley Brainard, MD

Timothy Daniels, MD

March 28, 2011
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please return to Sheryl Mroz via E-mail at smroz@biomimetics.com or by fax to 615-236-4966.

Richard Marks, MD

G. Andrew Murphy, MD

Steven Neufeld, MD

Michael Pinzur, MD

3-16-11

Steven Raikin, MD

Lew Schon, MD

James Sferra, MD

Naomi Shields, MD

Raymond Sullivan, MD

Date

Date

Date

Date

Date

Date

Date
After signing and dating, please return to Sheryl Mroz via fax at (619) 220-1966 or by fax to 619-226-4166.

Richard Marks, MD

Date

Dr. Andrew Murphy, MD

Date

Steven Neufeld, MD

Date

Michael J. MD

3/15/2011

Stuart Reven MD

Date

Lora S., MD

Date

Gail Smith, MD

Date

Lena Smith, MD

Date

Karen and Nathan MD

Date
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Lew Schon, MD

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3/17/2011

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Naomi Shields, MD

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Date

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3/21/11

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Raymond Sullivan, MD

3/31/11

Date
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Michael Swords, DO

Date

Brian Thomson, MD

Date

Troy Watson, MD

Date

Alastair Younger, MD

Date
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Michael Swords, DO

[Signature]

Date

Brian Thomson, MD

[Signature] 4/4/11

Date

Troy Watson, MD

[Signature]

Date

Alastair Younger, MD

[Signature]

Date
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Michael Swords, DO

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Brian Thomson, MD

Date

Troy Watson, MD

Date

3/28/11

Alastair Younger, MD

Date
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Michael Swords, DO

Brian Thomson, MD

Troy Watson, MD

Alastair Younger, MD

Date

Date

Date

16 MAR 2015

Date