

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 $\geq 50\%$ 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 optimized bone healing to achieve fusion.

Respectfully Submitted,

Augment Investigator Study Group.

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Name	Signature Date	Receipt Date
Abidi	28-Mar-11	29-Mar-11
Acevedo	28-Mar-11	29-Mar-11
Anderson, J.	16-Mar-11	16-Mar-11
Anderson, R.	29-Mar-11	30-Mar-11
Baumhauer	21-Mar-11	04-Apr-11
Berlet	01-Apr-11	04-Apr-11
Bibbo	11-Apr-11	11-Apr-11
Brainard	21-Mar-11	22-Mar-11
Daniels	18-Mar-11	18-Mar-11
DiGiovanni	18-Mar-11	18-Mar-11
Donatto	31-Mar-11	31-Mar-11
Easley	22-Mar-11	22-Mar-11
Elliott	14-Mar-11	16-Mar-11
Glazebrook	16-Mar-11	17-Mar-11
Granberry	29-Mar-11	30-Mar-11
Greisberg	28-Mar-11	29-Mar-11
Haddad	30-Mar-11	30-Mar-11
Hinz	31-Mar-11	01-Apr-11
Idusuyi	30-Mar-11	31-Mar-11
Jaakkola	05-Apr-11	05-Apr-11
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Le	01-Apr-11	05-Apr-11
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Marks	28-Mar-11	29-Mar-11
Murphy	01-Apr-11	01-Apr-11
Neufeld	31-Mar-11	07-Apr-11
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Raikin	15-Mar-11	17-Mar-11
Schon	17-Mar-11	18-Mar-11
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Thomson	04-Apr-11	04-Apr-11
Watson	28-Mar-11	29-Mar-11
Younger	16-Mar-11	17-Mar-11
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please return to Sheryl Mroz via E-mail at smroz@biomimetics.com or by fax to 615-236-4966.



Nicholas Abidi, MD

Date March 28, 2011

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John Anderson, MD

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Judith Baumhauer, MD

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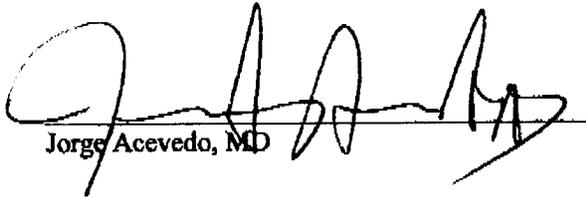
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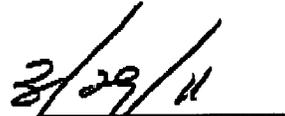
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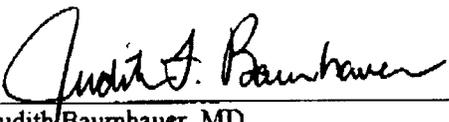
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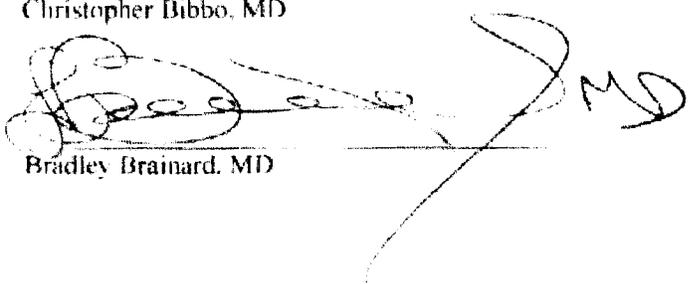
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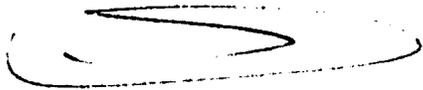
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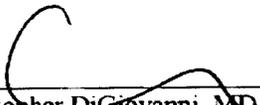


Timothy Daniels, MD

MAR. 18, 2011
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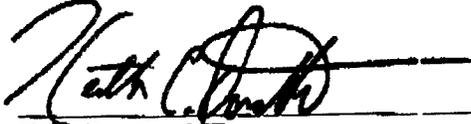
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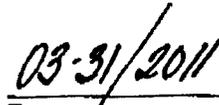
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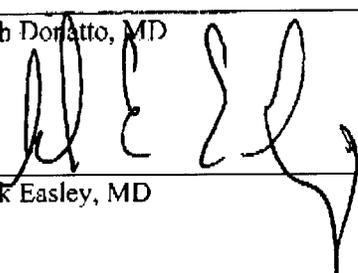
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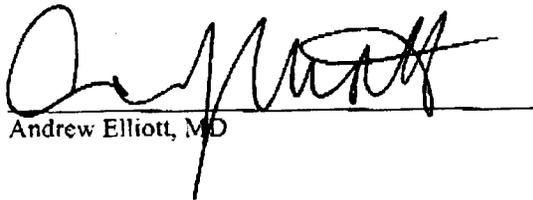
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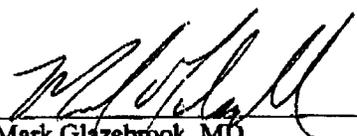
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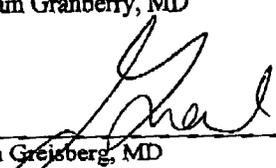
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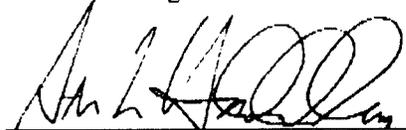
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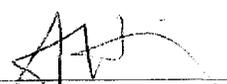
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3130/11

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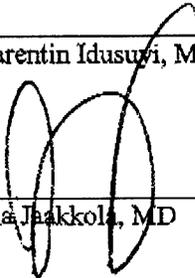
Sheldon Lin, MD

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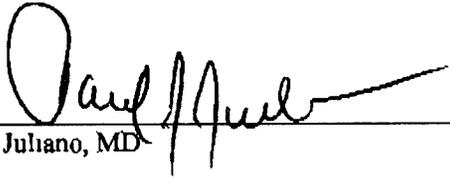
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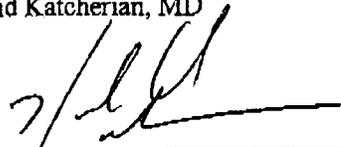
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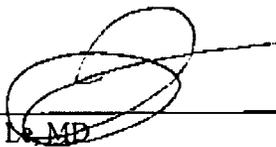
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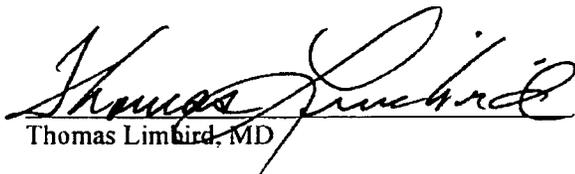
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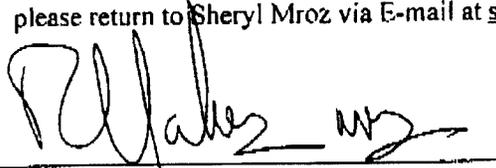
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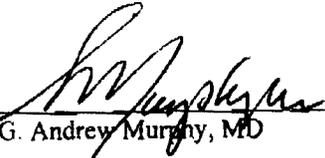
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Richard Marks, MD

Date



G. Andrew Murphy, MD

4/1/11
Date

Steven Neufeld, MD

Date

Michael Pinzur, MD

Date

Steven Raikin, MD

Date

Lew Schon, MD

Date

James Sferra, MD

Date

Naomi Shields, MD

Date

Raymond Sullivan, MD

Date

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SIGNATURE PAGE**

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Richard Marks, MD

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Steven Neufeld, MD



Date

3/31/2011

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Richard Marks, MD

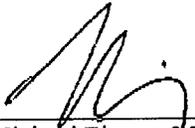
Date

G. Andrew Murphy, MD

Date

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Date



Michael Pinzur, MD

3-16-11

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Richard Marks, MD

Date

Andrew Murphy, MD

Date

Steven Neufeld, MD

Date

Michael F. ... MD

Date


Steven Kasper, MD

Date

3/15/2011

Eugene Scher, MD

Date

George Sutter, MD

Date

Nathan Sward, MD

Date

Raymond Sullivan, MD

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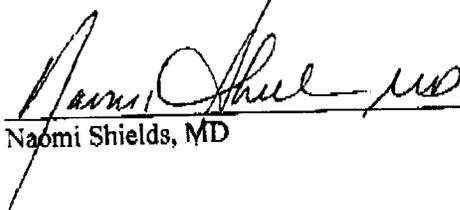
Date

Lew Schon, MD

Date

James Sferra, MD

Date



Naomi Shields, MD

Date
3/21/11

Raymond Sullivan, MD

Date

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Raymond Sullivan, MD

Date
3/31/11

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Michael Swords, DO

3/26/11

Date

Brian Thomson, MD

Date

Troy Watson, MD

Date

Alastair Younger, MD

Date

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Michael Swords, DO

Date



Brian Thomson, MD

4/4/11
Date

Troy Watson, MD

Date

Alastair Younger, MD

Date

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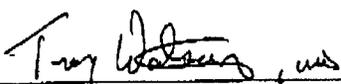
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Michael Swords, DO

Date

Brian Thomson, MD

Date



Troy Watson, MD

3/28/11

Date

Alastair Younger, MD

Date

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Michael Swords, DO

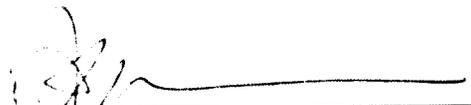
Date

Brian Thomson, MD

Date

Troy Watson, MD

Date



Alastair Younger, MD

Date 16/MAR/2011