HENSLER SURGICAL

To: To Whom It May Concern
From: Sean Hensler
Nicole Baldridge
Date: July 17, 2017
Subject: Regulatory Status of the Hensler Bone Collector

To Whom It May Concern:

The purpose for this communication is to notify you of the regulatory status of the Hensler Bone Collector being marketed for sale in the United States as a medical device. The Hensler Bone Collector™ device is intended for sterile, single-use in the collection of autograft captured from bone rongeurs or the clearing of tissue captured by surgical rongeurs, during surgical procedures.

The device may be used by specially qualified health care professionals including surgeons, physician assistants, first assists and certified scrub technicians.

Per the US Food and Drug Administration medical device regulations, the Hensler Bone Collector is as follows:

- Device Classification: Class II (special controls)
- FDA Establishment Registration Number: 3009657922
- Regulation Number: 880.6740
- Product Code: BYZ
- Submission Type: 510(K) Exempt
- Subject to good manufacturing practices and compliance to 21 CFR Part 820, Quality System Regulation

Hensler Surgical Products, LLC is in compliance with the Establishment Registration and Device Listing requirements per 21 CFR Part 807.20 as a manufacturer. The company is in full compliance with the medical device labeling regulations per 21 CFR Part 801. Safety and efficacy of the device has been established through design verification and validation testing including biocompatibility, physical integrity, sterility, packaging integrity, and physical evaluation of device/tissue interaction. Risk analyses have been performed and mitigations of risks identified with the design and manufacturing of the device have been mitigated per US and international standards.

If you have any questions about the Hensler Bone Collector regulatory status, please do not hesitate to contact us at 910.399.7380.

Sincerely,

DocuSigned by:
Sean Hensler
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Sean Hensler, Manager/Founder
Surgical Products, LLC

DocuSigned by:
Nicole M. Baldridge
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Nicole Baldridge, RA/QA Representative Hensler
President, Baldridge Consulting, LLC.