



**Panel Recommendation**

1. GENERIC TYPE OF DEVICE

Prosthetic device, bone heterograft

2. ADVISORY PANEL

Orthopaedic and Rehabilitation Devices Panel

3. IS DEVICE AN IMPLANT (21 CFR 860.3)?

Yes  No

4. INDICATIONS FOR USE IN THE DEVICE'S LABELING

The bone heterograft is intended to replace bone following surgery in the spinal column. The device may or may not be load bearing and may or may not require use of supplemental fixation. The device may or may not be used with bone grafting materials.

5. IDENTIFICATION OF ANY RISKS TO HEALTH PRESENTED BY DEVICE

General Risks may be associated with the following :

1. Failure to maintain source control, given the animal origin of the raw material; inadequate source control could result in transmission of zoonoses.
2. Processing that fails to render the raw material biocompatible, and fails to remove relevant antigens could result in eliciting an unacceptable level of immune response. Processing that is not fully validated and reproducible to assure the biocompatibility of implants could create same result.
3. Failure to control adventitious contamination, and/or failure to perform validated terminal sterilization could result in unintentional transmission of bacterial organisms.
4. Failure in performance of the device if the devices are not subjected to testing in accordance with established standards.

6. RECOMMENDED ADVISORY PANEL CLASSIFICATION AND PRIORITY

Classification 21 C.F.R. 888.3060

Priority (Class II or III Only) High

7. IF DEVICE IS AN IMPLANT, OR IS LIFE-SUSTAINING OR LIFE-SUPPORTING AND HAS BEEN CLASSIFIED IN A CATEGORY OTHER THAN CLASS III, EXPLAIN FULLY, THE REASONS FOR THE LOWER CLASSIFICATION WITH SUPPORTING DOCUMENTATION AND DATA

The class III designation was created during the Drug/Device transitional process in 1976 and to date, no products have cleared under this classification. However, several heterograft bone (more commonly referred to in recent years as xenograft) products with intended use both inside and outside the spine have cleared as implants in various Class II categories.

In the years since 1976, standards for testing and demonstration of both safety and performance have been developed and been recognized and accepted within the FDA product evaluation process under the 510k paradigm. In addition, FDA guidance documents addressing spinal implants and materials derived from animal sources have been developed and has become well established. 21 CFR 820, Quality System Regulation provides for validation and controls of the design of the Class II devices, as well as ongoing validation and process control requirements.

Additional testing methods and quality control criteria have been developed to support the market clearance of implants of bovine heterograft origin as class II devices. This includes both in-vitro and in-vivo testing for specific biological and potential antigenic characteristics and criteria to assure the standard of the source of animal material, the attached listing identifies these additional tests/criteria in italic script. It is suggested that these should be considered as requirements for Class II clearance, as special controls.

Relevant Guidance and Standards intended to expand on this position, and to address and provide mitigation are listed in Section 3.

8. SUMMARY OF INFORMATION, INCLUDING CLINICAL EXPERIENCE OR JUDGMENT, UPON WHICH CLASSIFICATION RECOMMENDATION IS BASED

Example of a bovine bone heterograft VBR device, which meets criteria defined in the relevant standards and guidance; Biocompatibility summary, mechanical test results, sterilization information are provided in Attachment 4.

Several implant products processed from bovine bone are cleared by FDA as Class II devices:

K051615 (08/15/05)

STERLING Cancellous Chips and Sterling Cancellous Cubes are indicated for bony void or gaps that are not intrinsic to the stability of the bony structure. They are indicated to be placed into bony voids or gaps of the skeletal system (e.g. extremities, spine, ilium and/or pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a void filler that remodels into the recipient's skeletal system.

K060253 (2/23/06), K052405 (11/16/05)

The STERLING Interference Screw HT is used to provide interference fixation in anterior cruciate ligament reconstruction using a bone-tendon-bone graft, and fixation during posterior cruciate ligament reconstruction utilizing a bone-tendon-bone graft.

K060253 (2/23/06), K050767 (06/09/05)

The STERLING Interference Screw ST is used to provide interference fixation of femoral and/or tibial tunnels in anterior cruciate ligament reconstruction using a soft tissue graft, and fixation during posterior cruciate ligament reconstruction utilizing soft tissue graft.

A number of bovine bone heterograft spine implant products and other implants with different surgical indications have been cleared under the EU Medical Device Directive 93/42 EC since 2000, and subsequently under the EU Commission Directive 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilizing tissues of animal origin.

9. IDENTIFICATION OF ANY NEEDED RESTRICTIONS ON THE USE OF THE DEVICE (e.g., special labeling, banning, or prescription use)

By or on the order of a licensed physician.; Single use only; Do not Resterilize

Complications: Although in-vitro and in-vivo testing showed no significant antigenic response to the device, there is a potential for immune response following implantation.

10. IF DEVICE IS RECOMMENDED FOR CLASS I, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM

*Justification / Comments*

- a. Registration / Device Listing \_\_\_\_\_
- b. Premarket Notification \_\_\_\_\_
- c. Records and Reports \_\_\_\_\_
- d. Good Manufacturing Practice \_\_\_\_\_

11. IF DEVICE IS RECOMMENDED FOR CLASS II, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM PREMARKET NOTIFICATION

- a. Exempt
- b. Not Exempt

Justifications/Comments General and Special Controls are required to assure safety and efficacy of devices in this classification.

12. EXISTING STANDARDS APPLICABLE TO THE DEVICE, DEVICE SUBASSEMBLIES (*Components*) OR DEVICE MATERIALS (*Parts and Accessories*)  
Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA

ISO/AAMI 11137 Sterilization of Healthcare Products- Requirements for Validation and Routine Control - Radiation Sterilization

Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices  
May 1, 1995, G95-1 (ISO 10993 Testing Requirements)

Guidance for Industry and FDA Reviewers - Immunotoxicity Testing Guidance, May 6, 1999

Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices)", 11/6/98

USP (85) LAL testing for Endotoxins

Guidance for Industry and FDA Staff Spinal System 510(k)s, May 3, 2004

ASTM F1717 Standard Test Methods for Static and Fatigue Testing for Spinal Implants in a Vertebrectomy Model.

ASTM F2077 Test Methods for Intervetebral Fusion Devices

13. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO:

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Health and Industry Programs (HFZ-215)  
1350 Piccard Drive  
Rockville, MD 20850

## OMB STATEMENT

Public reporting burden for this collection of information is estimated to average 1-2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services  
Food and Drug Administration, (HFZ-215)  
2094 Gaither Road  
Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.*

## INSTRUCTIONS FOR SUPPLEMENTAL DATA SHEET

1. The Supplemental Data Sheet should be prepared in conjunction with the General Device Questionnaire. The preparer should refer to Title 21 Part 860 of the Code of Federal Regulations for classification / reclassification definitions and procedures.
2. The Supplemental Data Sheet is designed to provide the device description, intended use, the risks of the device, the recommended class and the scientific support for the class and proposed level of controls.
3. The information requested by questions 1 through 8 must be provided for all devices.
4. Question 9 can be answered by referring to question 11 of the General Device Questionnaire.
5. Question 10 refers only to devices recommended for class I, and is a recommendation for exemptions from the General Controls listed.
6. Question 11 refers only to devices recommended for Class II.
7. Question 12 requests the listing of any existing standards for the device being classified. The standards to be listed could be standards drafted by professional groups, standards groups or manufacturers.
8. Send this completed form and the appropriate questionnaire to the address indicated in item 13.