DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 20 1996

Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Premarket Approval of Spine-Tech, Inc.'s
BAK™ Interbody Fusion System - ACTION

The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) a premarket approval order for the above referenced medical device (Tab B); and

(2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Susan Alpert, Ph.D., M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved ___ Disapproved ___ Date _____

Prepared by H.S. Rhodes, CDRH, HFZ-410, 6/16/96, 594-2036
Prepared by S.Niver, CDRH, HFZ-410, 9/12/96, 594-2036
Prepared by M.Melkerson, CDRH, HFZ-410, 9/12/96, 594-2036

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DRAFT

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. _____]

Spine-Tech, Inc.; PREMARKET APPROVAL OF BAK™ Interbody Fusion System with instrumentation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Spine-Tech, Inc., Minneapolis, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the BAK™ Interbody Fusion System with instrumentation. After reviewing the recommendation of the Orthopedic and Rehabilitation Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on September 20, 1996, of the approval of the application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

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FOR FURTHER INFORMATION CONTACT:

Mr. Mark N. Melkerson,

Center for Devices and Radiological Health (HFZ-410),

Food and Drug Administration,

9200 Corporate Blvd.,

Rockville, MD 20850,

301-594-2036.

SUPPLEMENTARY INFORMATION: On August 28, 1995, Spine-Tech, Inc., Minneapolis, MN 55439-2029, submitted to CDRH an application for premarket approval of the BAK™ Interbody Fusion System with instrumentation. This device is an intervertebral body fusion device. It is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). BAK™ devices are to be implanted via an open anterior or posterior approach. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

On May 23, 1996, the Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application.

On September 20, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity For Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: _____.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Richard Jansen, Pharm.D.
Vice President
Regulatory and Clinical Affairs
Spine-Tech, Inc.
7375 Bush Lake Road
Minneapolis, Minnesota 55439-2029

SEP 20 1996

Re: P950002
BAK™ Interbody Fusion System with instrumentation
Filed: August 28, 1995
Amended: February 22, 1996; April 15, 1996; April 19, 1996; April 22, 1996; May 10, 1996; July 26, 1996; August 12, 1996; August 23, 1996; September 11, 1996; and September 13, 1996.

Dear Dr. Jansen:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the BAK™ Interbody Fusion System with instrumentation. The device is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). BAK™ devices are to be implanted via an open anterior or posterior approach.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed) and the following condition that you provide updated promotional and advertising materials in your annual reports. You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the post-approval requirements in the enclosure, the post-approval reports must include the following information:

1. In order to assess the long-term performance of the BAK™ Interbody Fusion System, please conduct a post-approval study to obtain a total of 6 years of postoperative data from a minimum of 100 patients from each surgical approach group (i.e., anterior and posterior). These outcomes should be submitted to the FDA as part of your annual report. As stated in your PMA amendment received by FDA on September 11, 1996, your post-approval study will incorporate the following elements:

   a. inclusion of 150 patients implanted from the anterior approach and 150 patients implanted from the posterior approach. Patients will be selected from 3 to 6 sites which participated in the original IDE study. With an approximate 10% loss of patients to follow-up per each of the remaining four years, this should yield a minimum of 100 patients per anterior and posterior approach;

   b. collection of the following information biennially for each patient (because the designated patient population has already reached the two-year time point, patients will be evaluated at his/her 4 and 6-year time points):

      (1) a description of any surgical interventions which include reoperations, removals, revisions, and supplemental fixations;

      (2) radiographic assessment of fusion evaluated by an independent radiologist;

      (3) clinical assessment of pain and function using the scales employed in the original IDE study;

   c. use of following mechanisms to inform the patient of the post-approval study and to better assure an adequate number of patients are available at the completion of the study:

      (1) patient agreement to participate in the post-approval study by patient signing Letter of Agreement;

      (2) letters to participating physicians notifying them of impending due dates for patient assessment;

      (3) reimbursement for the physician and/or patient, as necessary;

      (4) reimbursement for costs of x-rays and/or physician office visits by patient's insurance and/or by Spine-Tech, Inc.; and

   d. annual assessment of physician compliance with the study.

2. Because of the unknown long-term device performance, particularly the resulting bony fusion characteristics, please conduct a post-approval study that focusses on the retrieval analyses

of any BAK™ device that is implanted and subsequently removed. This post-approval study is not limited to the patient population described in item 1 above. Histological information (e.g., bony ingrowth quality, bone quantity, response to potential wear debris, etc.) and metallurgical information (e.g., metal wear, deformation, cracking, corrosion, etc.) should be collected and reported in the annual reports. This post-approval study should continue for the duration of the study described in item 1 above.

Please note that the data obtained in these post-approval studies must be reflected in the labeling (via a PMA supplement) when they are completed.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling (i.e., package labels, package insert, patient information brochure, and surgical technique manuals) in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Mr. Mark N. Melkerson, Chief of the Orthopedic Devices Branch at (301) 594-2036.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure