

4160-QA

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

[DOCKET NO. 89M-0043]

MEADOX MEDICALS, INC.; PREMARKET APPROVAL OF STRYKER® DACRON®  
LIGAMENT PROSTHESIS

AGENCY: Food and Drug Administration.

54 FR 15556  
4/18/89

ACTION: Notice.

2798/89  
SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Meadox Medicals, Inc., Oakland, NJ, for premarket approval, under the Medical Device Amendments of 1976, of the Stryker® Dacron® Ligament Prosthesis. 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 of December 30, 1988, of the approval of the application.

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

ADDRESS: 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, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

89-71

1989M.0043

NAL 1

**FOR FURTHER INFORMATION CONTACT:**

Michael J. Blackwell,  
Center for Devices and Radiological Health (HFZ-410),  
Food and Drug Administration,  
8757 Georgia Ave.,  
Silver Spring, MD 20910,  
301-427-7156.

**SUPPLEMENTARY INFORMATION:** On August 5, 1985, Meadox Medicals, Inc., Oakland, NJ 07436, submitted to CDRH an application for premarket approval of the Stryker® Dacron® Ligament Prosthesis. The device is a prosthetic ligament fabricated from a combination of texturized and untexturized Dacron® yarns. The device consists of a knitted velour tube with a reinforcing core made up of four woven tapes. The device is placed intra-articularly by tibial and femoral attachments through bone tunnels. The device is indicated for use only as an intra-articular permanent replacement for the anterior cruciate ligament (ACL) of the knee for skeletally mature patients who have had at least one failed autogenous intra-articular reconstruction of their ACL.

On January 22, 1988, the Orthopedic and Rehabilitation Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On December 30, 1988, CDRH approved the application by a letter to the applicant from the Acting 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.

A copy of all approved labeling is available for public inspection at CDRH--contact Michael J. Blackwell (HFZ-410), address above.

#### OPPORTUNITY FOR ADMINISTRATIVE REVIEW

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), 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 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), 90 Stat. 554-555, 571 (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: April 7, 1989  
April 7, 1989

  
\_\_\_\_\_

Walter E. Gundaker  
Acting Deputy Director  
Center for Devices and Radiological Health

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Carolyn L. Conrad