



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 29, 1983

Food and Drug Administration  
8757 Georgia Avenue  
Silver Spring MD 20910

Mr. David L. Mullin  
President  
ACRA-CUT, INC.  
979 Main Street  
Acton, Massachusetts 01720

Ref: K833266A - ACRA-CUT<sup>R</sup> Standard and  
Disposable Cranial Perforator

Dated: November 18, 1983  
Received: December 9, 1983  
Regulatory class: II

Dear Mr. Mullin:

We have reviewed your premarket notification submission and have found the device to be substantially equivalent to devices introduced into interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). This product has been placed into the regulatory class shown above by a final regulation published in the Federal Register. Class I devices are regulated by the general control provisions of the Act applicable to all medical devices including annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act; class II devices are those for which future performance standards will be developed; class III devices are those which will be required to undergo premarket approval at some time in the future.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Section 800. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire. Also, the Federal Register will notify you of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you need further assistance on the labeling for your device, please contact the Office of Medical Devices, Division of Compliance Operations (HFK-110), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

Robert G. Britain  
Associate Director for  
Device Evaluation  
Office of Medical Devices  
National Center for Devices  
and Radiological Health