DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

MAR 4 1992

Ms. April Lavender
Manager, Regulatory Affairs
Cook, Incorporated
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402

Re: K913258 and K915409
Trade Name: Disposable Intraosseous Infusion Needles
Cook Intraosseous Access Needles
Regulatory Class: II

Dear Ms. Lavender:

In response to your appeal of January 21, 1992 of our January 7, 1992 letters for the above referenced Section 510(k) notifications, we have further reviewed the files and worked with the Food and Drug Administrations's (FDA) Center for Drug Evaluation and Research (CDER) to resolve the outstanding drug(s) issue described in those January 7 letters.

Based on a review of your labeling in the premarket notification, we have now concluded that the devices are substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the devices, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (act). The general controls provisions of the act include requirements for annual registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration. If you change your labeling, as described in 21CFR 807.81 (a)(3), a new premarket notification is required.

If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval) they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your devices as described. An FDA finding of substantial equivalence of your devices to pre-Amendments devices results in a classification for your devices and permits your devices to proceed to the market, but it does not mean that FDA approves your devices. Therefore, you may not promote or in any way represent your devices or their labeling as being approved by FDA. If you desire specific advice on the labeling for your devices, please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely Yours,

Philip J. Phillips
Interim Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health