GUIDANCE FOR EMERGENCY USE OF UNAPPROVED MEDICAL DEVICES (OCTOBER 22, 1985)

This guidance applies to the emergency use of an unapproved medical device. For the purpose of the guidance, an unapproved medical device is a device that is utilized for a purpose, condition, or use for which the device requires, but does not have, an approved application for premarket approval or an approved application for an IDE. An unapproved device may be used in human subjects only if it is approved for clinical testing under an IDE. An emergency need to use an unapproved device may occur when an IDE for the device does not exist, when a physician wants to use the device in a way not approved under the IDE, or when a physician or institution is not approved under the IDE.

In an orderly developmental process, the developer of a device (a physician, scientist, or manufacturer) anticipates the need to conduct clinical studies and uses the IDE to ensure that adequate preclinical testing has been done, that the appropriate subjects will be selected, that subjects participate only after providing informed consent, that the device will be used properly, that subjects will be monitored adequately after the device is used, and that complete scientific data will be collected promptly. These data form the basis for subsequent marketing approval of the device.

FDA recognizes that even during the earliest phases of device design, development, and testing, emergencies arise where an unapproved device offers the only alternative for saving the life of a dying patient, but an IDE has not yet been approved for the device or the use, or an IDE has been approved but the physician who wishes to use the device is not an investigator under the IDE. Using its enforcement discretion, FDA will not object if a physician chooses to use an unapproved device in such an emergency, provided that the physician later justifies to FDA that an emergency actually existed.

Each of the following conditions should exist for a situation to be considered an emergency:

- the patient is in a lifethreatening condition that needs immediate treatment;
- no generally acceptable alternative for treating the patient is available; and
- because of the immediate need to use the device, there is no time to use existing procedures to get FDA approval for the use.

FDA expects the physician to determine whether these criteria have been met, to assess the potential for benefits from the unapproved use of the device, and to have substantial reason to believe that benefits will