This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

3106

SEP 15 1995

CRITERIA FOR CATEGORIZATION OF INVESTIGATIONAL DEVICES

Category A: Experimental

_____ 1) Class III devices of a type for which no marketing application has been approved through the premarket approval (PMA) process for any indication for use. (For pre-amendments Class III devices, refer to the criteria under Category B); or

_____ 2) Class III devices that would otherwise be in Category B but have undergone significant modification for a new indication for use.

Category B: Non-experimental/Investigational

_____ 1) Devices, regardless of the classification, under investigation to establish substantial equivalence to a predicate device, i.e., to establish substantial equivalence to a previously/currently legally marketed device; or

_____ 2) Class III devices whose technological characteristics and indications for use are comparable to a PMA-approved device; or

_____ 3) Class III devices with technological advances compared to a PMA-approved device, i.e., a device with technological changes that represent advances to a device that has already received pre-market approval (generational changes); or

_____ 4) Class III devices that are comparable to a PMA-approved device which are under investigation for a new indication for use. For purposes of studying the new indication, no significant modifications to the device were required; or

_____ 5) Pre-amendments Class III devices that become the subject of an IDE after FDA requires premarket approval, i.e., no PMA was submitted or the PMA was denied; or

_____ 6) Non-significant risk device investigations for which FDA required the submission of an IDE.

_____

Branch Chief (date)

For Category A determinations only:

_____

IDE Staff concurrence (date)