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SEP 15 1995IDE Memorandum - #D95-2
Attachment B - Page 1CRITERIA FOR CATEGORIZATION OF
INVESTIGATIONAL DEVICESCategory 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)