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Philips Medical Systems 2154 '03 OCT 15 A9:20

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket 2003D-0319: Draft Guidance for Industry and FDA Staff—Premarket Assessment of Pediatric Medical Devices

14 October 2003

To Whom It May Concern:

Philips Medical Systems, Cardiac and Monitoring Systems, is submitting comments to the proposed FDA Docket 2003D-0319: Draft Guidance for Industry and FDA Staff—Premarket Assessment of Pediatric Medical Devices.

We would like to suggest the following modifications:

#	Issue	Impact	Recommendations
1	Age Ranges of Pediatrics Subgroups (Table 1, page 3)	The proposed age range of adolescents as 12-21 years of age is inconsistent with the Dept. of Health and Human Services (CMS) range of 12 to <18 years of age.	We recommend that the adolescent range be adjusted to <18 years of age to be consistent with CMS policies.
2	Neonate vs. newborn (Table 1, page 3)	Throughout the guidance document there is an inconsistent use of "newborn" vs. "neonate".	Clarify newborn vs. neonate for consistency.
3	Low birth rate populations (page 3)	Low birth rate subgroups are not specifically tied to Table 1 or to terminology used throughout guidance.	Clarify low birthrates by connecting the low birth rate subgroup to neonates/newborns.

We respectfully ask that the FDA consider the above-mentioned recommendations to clarify the guidance document. Thank you for allowing us the opportunity to comment.

Sincerely,

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2003D-0319

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