

Classification Rationale

Product Family Apgar Timer			
Type	Rule	Class	Additional Information
Non-Invasive	Rule 1		
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Active	Rule 1 & 12		Monitors – Time Elapsed
Invasive	No		3
Special	No		

Flow chart includes: Yes or No

Classified by:

Date:

06 1 05 12008

The Device does no administer or exchange energy, fluids, solids or gases. It is there as a guide to time elapsed so that APGAR scoring can be used.

APGAR scores are used at 1 minute: 5 minute: and 10 minute intervals from the birth of the infant.

This device is a simple second and minute counter that is started around birth and gives an audio sound to remind the clinician or midwife to check the time .

Real time of birth is noted by other means.