

K023082 BABYCAREMar 3, 2003
167 days to decisionK023082 · Product code: **HEP** · Radiology
Source: <https://www.510kdatabase.net/k023082/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Monitor, Blood-flow, Ultrasonic (HEP)
Date received	Sep 17, 2002
Decision date	Mar 3, 2003
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bionet Company, Ltd.
Location	Seoul, KR
Contact	JAY MANSOUR
510(k) history	3 submissions · 3 cleared · 2001-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k023082/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 19, 2026