

K010156 SLEEP PAT 200 DEVICEJun 19, 2002
519 days to decisionK010156 · Product code: **MNR** · Anesthesiology
Source: <https://www.510kdatabase.net/k010156/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Jan 16, 2001
Decision date	Jun 19, 2002
Days to decision	519 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Itamar Medical (C.M.) 1997 , Ltd.
Location	Ginot Shomron 44853, IL
Contact	GEORGE H MYERS
510(k) history	3 submissions · 3 cleared · 2001-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010156/> 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 25, 2026