

K973011 BPX80 BIO-PUMP (BPX80)Feb 25, 1998
196 days to decisionK973011 · Product code: **KFM** · CardiovascularSource: <https://www.510kdatabase.net/k973011/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Aug 13, 1997
Decision date	Feb 25, 1998
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Bio-Medicus, Inc.
Location	Eden Prairie, MN, US
Contact	THOMAS K JOHNSEN
510(k) history	13 submissions · 13 cleared · 1992-1998

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