

**K990284 BAYLIS MEDICAL RF SEPTOSTOMY GENERATOR,
 NYKANEN RF SEPTOSTOMY CATHETER, BAYLIS MEDICAL
 CONNECTOR CABLE**

Feb 1, 2001
 734 days to decision

K990284 · Product code: **DXF** · Cardiovascular
 Source: <https://www.510kdatabase.net/k990284/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Septostomy (DXF)
Date received	Jan 29, 1999
Decision date	Feb 1, 2001
Days to decision	734 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Baylis Medical Co., Inc.
Location	Mississauga, CA
Contact	KRIS SHAH
510(k) history	28 submissions · 28 cleared · 1998-2013

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k990284/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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