

**K020634 MODIFICATION TO ATRIUM MEDICAL CORPORATION
CLEARWAY PTFE BALLOON CATHETER**May 8, 2002
70 days to decisionK020634 · Product code: **DXE** · Cardiovascular
Source: <https://www.510kdatabase.net/k020634/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Embolectomy (DXE)
Date received	Feb 27, 2002
Decision date	May 8, 2002
Days to decision	70 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Atrium Medical Corp.
Location	Mchenry, IL, US
Contact	JOSEPH P DE PAOLA
510(k) history	63 submissions · 61 cleared · 1981-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k020634/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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