

K963335 HARMAC BALLOON WEDGE PRESSURE CATHETEROct 16, 1997
475 days to decisionK963335 · Product code: **DQO** · Cardiovascular
Source: <https://www.510kdatabase.net/k963335/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Jun 28, 1996
Decision date	Oct 16, 1997
Days to decision	475 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Harmac Medical Products, Inc.
Location	Buffalo, NY, US
Contact	JOSEPH KONIECZNY
510(k) history	8 submissions · 8 cleared · 1995-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963335/> 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 July 2, 2026