FDA 510(k) Premarket Notification

K963335 HARMAC BALLOON WEDGE PRESSURE CATHETER

CLEARED

Oct 16, 1997
475 days to decision

K963335 · 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