

K964968 MR EXTENSION SET (001)Feb 27, 1997
77 days to decisionK964968 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k964968/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Dec 12, 1996
Decision date	Feb 27, 1997
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	University of Michigan
Location	Ann Arbor, MI, US
Contact	MARTIN R PRINCE, MD, PH.D.
Website	http://www.mgoblue.com/sports/m-basketball/mich-m-basketball-body.html
510(k) history	2 submissions · 2 cleared · 1990-1997

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