

**K011656 HYPERFORM OCCLUSION BALLOON SYSTEM,
MODEL 104-4470, 104-4471, 104-4770, 104-4771**Jun 20, 2001
22 days to decisionK011656 · Product code: **MJN** · Cardiovascular
Source: <https://www.510kdatabase.net/k011656/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	May 29, 2001
Decision date	Jun 20, 2001
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Micro Therapeutics, Inc.
Location	Aliso Viejo, CA, US
Contact	EBEN GORDON
510(k) history	51 submissions · 50 cleared · 1994-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011656/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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