

K833616 OLBERT CATHETER SYSTEMDec 26, 1983
74 days to decisionK833616 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k833616/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Oct 13, 1983
Decision date	Dec 26, 1983
Days to decision	74 days
Third-party review	No

APPLICANT

Company	Madox Medicals, Div. Boston Scientific Corp.
Location	Mchenry, IL, US
Website	https://www.bostonscientific.com
510(k) history	53 submissions · 47 cleared · 1976-1997

Madox Medicals, Div. Boston Scientific Corp. is a medical device manufacturer based in McHenry, US. Now part of Boston Scientific, the brand maintains a historical record of FDA 510(k) clearances. The company received FDA 510(k) clearances from total submissions between 1976 and 1997. Cardiovascular devices dominated the company's portfolio, representing 81% of all submissions. Notable cleared products include vascular grafts, balloon catheters, and cardiovascular patches used in surgical and interventional procedures. Madox Medicals is no longer active in FDA 510(k) su...