FDA 510(k) Premarket Notification

K032390 MODIFICATION TO EBI TARGETCATH FLUORO-GUIDED STEERABLE CATHETER SYSTEM

CLEARED

Aug 29, 2003
25 days to decision

K032390 · Product code: **BSO** · Anesthesiology
Source: https://www.510kdatabase.net/k032390/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Conduction, Anesthetic (BSO)
Date received	Aug 4, 2003
Decision date	Aug 29, 2003
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ebi, L.P.**
Location	Parsippany, NJ, US
Contact	BARRY SANDS
510(k) history	95 submissions · 94 cleared · 1997-2010