FDA 510(k) Premarket Notification

K813345 CRITIKON I.V. CATHETER PLACEMENT UNIT

CLEARED

Jan 12, 1982
48 days to decision

K813345 · Product code: **FOZ** · General Hospital
Source: https://www.510kdatabase.net/k813345/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Nov 25, 1981
Decision date	Jan 12, 1982
Days to decision	48 days
Third-party review	No

APPLICANT

Company	**Critikon Company, LLC**
Location	Mchenry, IL, US
510(k) history	51 submissions · 51 cleared · 1979-2000