FDA 510(k) Premarket Notification

CLEARED

K964021 INTRAMED SIDE BRANCH OCCLUSION (SBO) SYSTEM (700095 AND 700099)

Mar 27, 1997
171 days to decision

K964021 · Product code: **HCG** · Neurology
Source: https://www.510kdatabase.net/k964021/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Oct 7, 1996
Decision date	Mar 27, 1997
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Baxter Edwards**
Location	Irvine, CA, US
Contact	PAULA A TORRIANNI
510(k) history	11 submissions · 10 cleared · 1993-2000