FDA 510(k) Premarket Notification

K002181 GDC ULTRASOFT COIL

CLEARED

Aug 11, 2000
23 days to decision

K002181 · Product code: **HCG** · Neurology
Source: https://www.510kdatabase.net/k002181/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Jul 19, 2000
Decision date	Aug 11, 2000
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific, Target**
Location	Freemont, CA, US
Contact	JAMES LEATHLEY
510(k) history	19 submissions · 19 cleared · 1999-2003