FDA 510(k) Premarket Notification

K890746 MYOTEST DBS NERVE STIMULATOR

CLEARED

Jul 14, 1989
151 days to decision

K890746 · Product code: **BXN** · Anesthesiology
Source: https://www.510kdatabase.net/k890746/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Battery-powered (BXN)
Date received	Feb 13, 1989
Decision date	Jul 14, 1989
Days to decision	151 days
Third-party review	No

APPLICANT

Company	**Biometer Intl. A/S**
Location	Denmark, DK
Contact	FLEMMING HIMMELSTRUP
510(k) history	9 submissions · 9 cleared · 1986-1993