FDA 510(k) Premarket Notification

K832916 INIVOX ELECTRODE/CATHETER SYS

CLEARED

Nov 14, 1983
77 days to decision

K832916 · Product code: **LLE** · Neurology
Source: https://www.510kdatabase.net/k832916/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Spinal-cord, Implanted For Peripheral Vascular Disease (LLE)
Date received	Aug 29, 1983
Decision date	Nov 14, 1983
Days to decision	77 days
Third-party review	No

APPLICANT

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