FDA 510(k) Premarket Notification

K982950 FINE WIRE ELECTRODE MMODEL NUMBERS 221-14-730, 221-24-730, 221-14-550, 221-24-550

CLEARED

Jun 22, 1999
305 days to decision

K982950 · Product code: **IKT** · Neurology
Source: https://www.510kdatabase.net/k982950/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Needle, Diagnostic Electromyograph (IKT)
Date received	Aug 21, 1998
Decision date	Jun 22, 1999
Days to decision	305 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Chalgren Enterprises, Inc.**
Location	Gilroy, CA, US
Contact	RICHARD KAISER
510(k) history	21 submissions · 21 cleared · 1989-1999