FDA 510(k) Premarket Notification

K943468 LEKSELL SURGIPLAN

CLEARED

Jan 20, 1995
185 days to decision

K943468 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k943468/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jul 19, 1994
Decision date	Jan 20, 1995
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Elekta Instruments, Inc.**
Location	Tucker, GA, US
Contact	TOM PARKER
510(k) history	8 submissions · 8 cleared · 1992-1999