FDA 510(k) Premarket Notification

K031980 MODIFICATION TO LEKSELL STEREOTACTIC SYSTEM

CLEARED

Jul 25, 2003
29 days to decision

K031980 · Product code: **HAW** · Radiology
Source: https://www.510kdatabase.net/k031980/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jun 26, 2003
Decision date	Jul 25, 2003
Days to decision	29 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Elekta Instrument AB**
Location	Lake Forest, CA, US
Contact	PETER LOWENDAHL
510(k) history	35 submissions · 35 cleared · 1996-2019

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k031980/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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