FDA 510(k) Premarket Notification

K022074 SPHERZ

CLEARED

Aug 13, 2002
48 days to decision

K022074 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k022074/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jun 26, 2002
Decision date	Aug 13, 2002
Days to decision	48 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**I.Z.I. Corp.**
Location	Owings Mills, MD, US
Contact	HELEN ZINREICH
510(k) history	7 submissions · 7 cleared · 1992-2002

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k022074/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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