

K861629 KOMAI CT-STEREOTACTIC APPARATUS AND ACCESSORIESAug 12, 1986
105 days to decisionK861629 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k861629/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Apr 29, 1986
Decision date	Aug 12, 1986
Days to decision	105 days
Third-party review	No

APPLICANT

Company	Downs Surgical , Ltd.
Location	Mchenry, IL, US
Contact	JOHN FORSTER
510(k) history	60 submissions · 60 cleared · 1980-1990

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k861629/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 22, 2026