

K993766 HELAX-TMS V 5.0 RADIATION THERAPY TREATMENT PLANNING SYSTEM

Dec 8, 1999
30 days to decision

K993766 · Product code: **MUJ** · Radiology
Source: <https://www.510kdatabase.net/k993766/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Nov 8, 1999
Decision date	Dec 8, 1999
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Helax AB
Location	Uppsala, SE
Contact	E.S. MARTELL
510(k) history	3 submissions · 3 cleared · 1997-1999

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Device record: <https://www.510kdatabase.net/k993766/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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