

K982463 EXTRACRANIAL RADIOTHERAPY SYSTEMSep 30, 1998
77 days to decisionK982463 · Product code: IYE · Radiology
Source: <https://www.510kdatabase.net/k982463/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Accelerator, Linear, Medical (IYE) |
| Date received | Jul 15, 1998 |
| Decision date | Sep 30, 1998 |
| Days to decision | 77 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Howmedica, Inc. |
| Location | Rutherford, NJ, US |
| Contact | VIVIAN KELLY |
| 510(k) history | 36 submissions · 29 cleared · 1994-1999 |

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