

K063230 INTEGRA RADIONICS IMAGEFUSION 3Dec 21, 2006
57 days to decisionK063230 · Product code: **MUJ** · Radiology
Source: <https://www.510kdatabase.net/k063230/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, Planning, Radiation Therapy Treatment (MUJ) |
| Date received | Oct 25, 2006 |
| Decision date | Dec 21, 2006 |
| Days to decision | 57 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Integra Radionics, Inc. |
| Location | Burlington, MA, US |
| Contact | KEVIN J O'CONNELL |
| 510(k) history | 10 submissions · 10 cleared · 2006-2011 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k063230/> 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 17, 2026