

K032315 IOP8 INTRA OPERATIVE PROBENov 18, 2004
479 days to decisionK032315 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k032315/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Transducer, Ultrasonic, Diagnostic (ITX) |
| Date received | Jul 28, 2003 |
| Decision date | Nov 18, 2004 |
| Days to decision | 479 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Huntleigh Healthcare, Inc. |
| Location | Eatontown, NJ, US |
| Contact | B.J. COLLEYPRIEST |
| 510(k) history | 14 submissions · 14 cleared · 1993-2004 |

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