

K100468 ZEISS INFRARED 800 WITH FLOW 800 OPTIONMar 3, 2010
13 days to decisionK100468 · Product code: IZI · Radiology
Source: <https://www.510kdatabase.net/k100468/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Angiographic (IZI) |
| Date received | Feb 18, 2010 |
| Decision date | Mar 3, 2010 |
| Days to decision | 13 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Carl Zeiss Surgical GmbH |
| Location | North Attleboro, MA, US |
| Contact | JUDITH BRIMACOMBE |
| 510(k) history | 4 submissions · 4 cleared · 2005-2012 |

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