

K013327 CTS-415Dec 14, 2001
70 days to decisionK013327 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k013327/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Echo, Ultrasonic (IYO) |
| Date received | Oct 5, 2001 |
| Decision date | Dec 14, 2001 |
| Days to decision | 70 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Shantou Institute of Ultrasonic Instruments |
| Location | Walnut Creek, CA, US |
| Contact | BOB LEIKER |
| 510(k) history | 11 submissions · 11 cleared · 1997-2012 |

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