FDA 510(k) Premarket Notification

# K812435 DATAPASS

**CLEARED**

Jan 28, 1982
156 days to decision

K812435 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k812435/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Echo, Ultrasonic (IYO) |
| Date received | Aug 25, 1981 |
| Decision date | Jan 28, 1982 |
| Days to decision | 156 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **General Electric Co.** |
| Location | Mchenry, IL, US |
| 510(k) history | 254 submissions · 254 cleared · 1976-2011 |

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k812435/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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