

K994385 BABY FACEMar 16, 2000
79 days to decisionK994385 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k994385/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Echo, Ultrasonic (IYO) |
| Date received | Dec 28, 1999 |
| Decision date | Mar 16, 2000 |
| Days to decision | 79 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Sonora Medical Systems |
| Location | Indianapolis, IN, US |
| Contact | COLLEEN HITTLE |
| 510(k) history | 2 submissions · 2 cleared · 2000-2001 |

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