

K946300 DOPPLEX SURGICAL PROBESJul 26, 1995
210 days to decisionK946300 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k946300/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Transducer, Ultrasonic, Diagnostic (ITX) |
| Date received | Dec 28, 1994 |
| Decision date | Jul 26, 1995 |
| Days to decision | 210 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Hne Healthcare, Inc. |
| Location | Manalapan, NJ, US |
| Contact | AUDREY WITKO |
| 510(k) history | 2 submissions · 2 cleared · 1995-1996 |

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