

K231783 VitroPRONov 14, 2023
151 days to decisionK231783 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k231783/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Transducer, Ultrasonic, Diagnostic (ITX) |
| Date received | Jun 16, 2023 |
| Decision date | Nov 14, 2023 |
| Days to decision | 151 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | CIVCO Medical Instruments Co., Inc. |
| Location | Walker, MI, US |
| Contact | James Leong |
| 510(k) history | 29 submissions · 29 cleared · 1982-2023 |

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