

K134035 TRANSONIC HCM 103 SYSTEMSep 17, 2014
260 days to decisionK134035 · Product code: **DXG** · CardiovascularSource: <https://www.510kdatabase.net/k134035/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Computer, Diagnostic, Pre-programmed, Single-function (DXG) |
| Date received | Dec 31, 2013 |
| Decision date | Sep 17, 2014 |
| Days to decision | 260 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Transonic Systems, Inc. |
| Location | Ithaca, NY, US |
| Contact | NAVEEN THURAMALLA |
| 510(k) history | 16 submissions · 16 cleared · 1988-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k134035/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 4, 2026