

K151127 high StationDec 8, 2015
224 days to decisionK151127 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k151127/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Measurement, Blood-pressure, Non-invasive (DXN) |
| Date received | Apr 28, 2015 |
| Decision date | Dec 8, 2015 |
| Days to decision | 224 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Higi Sh, LLC |
| Location | Monrovia, CA, US |
| Contact | Colin Hill |
| 510(k) history | 2 submissions · 2 cleared · 2015-2017 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151127/> 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 May 31, 2026