

K140360 HEALTH KIOSKApr 10, 2015
422 days to decisionK140360 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k140360/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Measurement, Blood-pressure, Non-invasive (DXN) |
| Date received | Feb 12, 2014 |
| Decision date | Apr 10, 2015 |
| Days to decision | 422 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Engagementhealth, LLC |
| Location | Hialeah, FL, US |
| Contact | JORGE MILLAN |
| 510(k) history | 1 submissions · 1 cleared · 2015-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140360/> 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