

K093907 WELCH ALLYN NON INVASIVE BLOOD PRESSURE (NIBP) DEVICEApr 14, 2010
113 days to decisionK093907 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k093907/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | System, Measurement, Blood-pressure, Non-invasive (DXN) |
| Date received | Dec 22, 2009 |
| Decision date | Apr 14, 2010 |
| Days to decision | 113 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Welch Allyn, Inc. |
| Location | Mchenry, IL, US |
| Contact | HUY DOAN |
| Website | http://www.welchallyn.com/ |
| 510(k) history | 111 submissions · 111 cleared · 1977-2025 |

Welch Allyn, Inc. is a medical device manufacturer based in McHenry, US. The company specializes in patient monitoring and diagnostic equipment for healthcare settings. Welch Allyn has maintained a strong FDA 510(k) regulatory record since 1977. The company has received FDA 510(k) clearances from total submissions. Cardiovascular monitoring devices represent the dominant category in recent clearances, including the Connex vital signs monitor series and central station systems. The company's latest clearance in 2025 demonstrates continued regulatory activity and product in...

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Device record: <https://www.510kdatabase.net/k093907/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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