

K952289 WELCH ALLYN FIBER OPTIC HEADLIGHTJul 14, 1995
59 days to decisionK952289 · Product code: **HPQ** · Ophthalmic
Source: <https://www.510kdatabase.net/k952289/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Headlamp, Operating, Ac-powered (HPQ) |
| Date received | May 16, 1995 |
| Decision date | Jul 14, 1995 |
| Days to decision | 59 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Welch Allyn, Inc. |
| Location | Mchenry, IL, US |
| Contact | MARY KAY TESORO |
| 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...
