

K120028 AQUAMAX (ETAFILCON A) DISPOSABLE SOFT CONTACT LENSESApr 17, 2012
104 days to decisionK120028 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k120028/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Lenses, Soft Contact, Daily Wear (LPL) |
| Date received | Jan 4, 2012 |
| Decision date | Apr 17, 2012 |
| Days to decision | 104 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Pegavision Corporation |
| Location | Taoyuan City, TW |
| Contact | TONY HSU |
| Website | https://www.pegavision.com |
| 510(k) history | 12 submissions · 12 cleared · 2012-2026 |

Pegavision Corporation is a contact lens manufacturer with a manufacturing facility in Taoyuan City, Taiwan. The company specializes in soft contact lens design and production for vision correction. Pegavision has received FDA 510(k) clearances from total submissions since 2012. The company focuses exclusively on Ophthalmic devices, with a strong track record in daily disposable and scheduled replacement soft contact lenses. The latest clearance was in 2026, confirming active regulatory engagement. The company's product portfolio includes daily disposable soft contact len...