

**K260935 Stelo Glucose Biosensor System**Jun 12, 2026  
84 days to decisionK260935 · Product code: **SBH** · Chemistry  
Source: <https://www.510kdatabase.net/k260935/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Integrated Continuous Glucose Monitor For Non-intensive Glucose Management, Over-the-counter (SBH) |
| Date received         | Mar 20, 2026   |
| Decision date         | Jun 12, 2026   |
| Days to decision      | 84 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Dexcom, Inc.</b>   |
| Location       | San Diego, CA, US   |
| Contact        | Neeta Sharma  |
| Website        | <a href="https://www.dexcom.com">https://www.dexcom.com</a> |
| 510(k) history | 27 submissions · 24 cleared · 2014-2026                     |

Dexcom, Inc. is a medical device company headquartered in San Diego, US. The company specializes in continuous glucose monitoring systems and related chemistry devices. Dexcom has received FDA 510(k) clearances from total submissions since its first clearance in 2014. The company's regulatory portfolio is dominated by chemistry devices, which account for 92% of submissions. The latest clearance was granted in 2026, reflecting active ongoing development and regulatory engagement. The company's cleared device portfolio centers on continuous glucose monitoring technology. Re...