

**K230712 SG Lanset I, SG Lancets, Soft Lancets**Dec 6, 2023  
266 days to decisionK230712 · Product code: **QRK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230712/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature (QRK)
Date received	Mar 15, 2023
Decision date	Dec 6, 2023
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sewon Medical Co.</b>
Location	Busan-Si, KR
Contact	Ji-yeon Kim
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Smb Korea</b>
Contact	Kyung-hwan Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230712/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026