

K250984 Maestro System (REF100)Jun 27, 2025
88 days to decisionK250984 · Product code: **QZB** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250984/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Software Controlled Endoscope And Instrument Holder (QZB)
Date received	Mar 31, 2025
Decision date	Jun 27, 2025
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Moon Surgical
Location	Paris, FR
Contact	Anne Osdoit
510(k) history	4 submissions · 4 cleared · 2022-2025

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