

K200305 NPsealMay 26, 2020
110 days to decisionK200305 · Product code: **OKO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k200305/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Non-powered Suction Apparatus (OKO)
Date received	Feb 6, 2020
Decision date	May 26, 2020
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Guard Medical, Inc.
Location	New York, NY, US
Contact	Machiel Van der Leest
510(k) history	7 submissions · 7 cleared · 2020-2025

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