

K182722 XLR8 Abdominal Wound Dressing KitSep 27, 2019
364 days to decisionK182722 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k182722/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Sep 28, 2018
Decision date	Sep 27, 2019
Days to decision	364 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Genadyne Biotechnologies
Location	Hicksville, NY, US
Contact	Swara Vashi
510(k) history	2 submissions · 2 cleared · 2019-2020

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