

K181204 RENASYS Y-ConnectorJan 10, 2019
248 days to decisionK181204 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181204/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	May 7, 2018
Decision date	Jan 10, 2019
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	RENASYS TOUCH

APPLICANT

Company	Smith & Nephew Medical Limited
Location	Hull, GB
Contact	Sam Greenhalgh
510(k) history	20 submissions · 20 cleared · 2016-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181204/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026