FDA 510(k) Premarket Notification

K181822 RENASYS Touch

CLEARED

Mar 21, 2019
255 days to decision

K181822 · Product code: **OMP** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k181822/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Jul 9, 2018
Decision date	Mar 21, 2019
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	RENASYS Y-Connector

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Smith and Nephew**
Contact	Kulsum Master

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov