FDA 510(k) Premarket Notification

K201930 Nanum Syringe

CLEARED

Jan 17, 2021
191 days to decision

K201930 · Product code: **FMF** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k201930/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jul 10, 2020
Decision date	Jan 17, 2021
Days to decision	191 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nanum Company Co., Ltd.**
Location	Daegu, KR
Contact	Jeong Ung Jong
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Plusglobal**
Contact	Peter Chung

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