FDA 510(k) Premarket Notification

K190962 Bella-mu

CLEARED

Feb 3, 2020
297 days to decision

K190962 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k190962/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Apr 12, 2019
Decision date	Feb 3, 2020
Days to decision	297 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**U-Needle B.V.**
Location	Enschede, NL
Contact	Gert Veldhuis
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Medical Device Academy, Inc.**
Contact	Robert Packard

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