FDA 510(k) Premarket Notification

K190144 MucoPEG

CLEARED

Nov 5, 2019
280 days to decision

K190144 · Product code: **LFD** · Dental
Source: https://www.510kdatabase.net/k190144/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saliva, Artificial (LFD)
Date received	Jan 29, 2019
Decision date	Nov 5, 2019
Days to decision	280 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sunbio, Inc.**
Location	Gunpo-Si, KR
Contact	Sun S. Kim
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Emergo by UL**
Contact	Stuart R. Goldman

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