

K211026 Minitube Dentasleeve Protective Barrier SleevesAug 3, 2021
119 days to decisionK211026 · Product code: **PEM** · Dental
Source: <https://www.510kdatabase.net/k211026/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dental Barriers And Sleeves (PEM)
Date received	Apr 6, 2021
Decision date	Aug 3, 2021
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Minitube AB
Location	Trångsviken, SE
Contact	Bengt Myhrman
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Mdi Consultants, Inc.
Contact	Vaibhav Arvind Rajal

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211026/> 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 May 25, 2026