FDA 510(k) Premarket Notification

K201098 Ambu Duodeno System

CLEARED

Jul 17, 2020
84 days to decision

K201098 · Product code: **FDT** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k201098/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Duodenoscope And Accessories, Flexible/rigid (FDT)
Date received	Apr 24, 2020
Decision date	Jul 17, 2020
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ambu Innovation GmbH**
Location	Kissing, DE
Contact	Oliver V Ruepprecht
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Ambu, Inc.**
Contact	Sanjay Parikh

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