FDA 510(k) Premarket Notification

K211212 LoFric Elle

CLEARED

Feb 17, 2022
300 days to decision

K211212 · Product code: **EZD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k211212/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Apr 23, 2021
Decision date	Feb 17, 2022
Days to decision	300 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dentsply Sirona**
Location	York, PA, US
Contact	Rebecca Sporer
Website	https://www.dentsplysirona.com
510(k) history	65 submissions · 65 cleared · 2016-2026

Dentsply Sirona is an American dental equipment manufacturer and consumables producer headquartered in York, US. The company markets products in over 120 countries and operates factories across 21 nations. Dentsply Sirona has received FDA 510(k) clearances from total submissions since 2016. Dental devices represent 78% of the company's regulatory submissions, reflecting its core focus on laboratory equipment, specialty products, and consumables including abutments, CAD/CAM blocks, and restorative materials. The company's latest clearance in 2026 demonstrates continued reg...