FDA 510(k) Premarket Notification

CLEARED

K221377 SteriKing LT-Blueline Pouches with Tyvek

Dec 22, 2022
224 days to decision

K221377 · Product code: **FRG** · General Hospital
Source: https://www.510kdatabase.net/k221377/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	May 12, 2022
Decision date	Dec 22, 2022
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Wipak OY**
Location	Nastola, FI
Contact	Hanna Marttila
510(k) history	7 submissions · 7 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	**Compliance Systems International**
Contact	Amanda Singleton

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