FDA 510(k) Premarket Notification

CLEARED

K230759 SafeLan® (2 models/SafeLan 26G, SafeLan 30G), SafeLan®-Pro (1 model/SafeLan®-Pro)

Jun 13, 2023
85 days to decision

K230759 · Product code: **QRK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k230759/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature (QRK)
Date received	Mar 20, 2023
Decision date	Jun 13, 2023
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bosungmeditech Co., Ltd.**
Location	Wonju, KR
Contact	Yang Ho Song
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Andrew Chun**
Contact	Andrew Chun

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