CLEARED

K190563 4CIS PEEK PLIF Cage, 4CIS Pebble Beach PEEK PLIF Cage, 4CIS Torrey Pines PEEK TLIF Cage, 4CIS Dunes PEEK DLIF Cage, 4CIS Augusta PEEK ALIF Cage

Sep 18, 2019
197 days to decision

K190563 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k190563/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 5, 2019
Decision date	Sep 18, 2019
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Solco Biomedical Co., Ltd.**
Location	Bethesda, MD, US
Contact	Il Kim
510(k) history	17 submissions · 17 cleared · 2005-2024