FDA 510(k) Premarket Notification

K032242 PERSONNA PLUS SAFETY SCALPEL SYSTEM

CLEARED

Sep 23, 2003
64 days to decision

K032242 · Product code: **GES** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k032242/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blade, Scalpel (GES)
Date received	Jul 21, 2003
Decision date	Sep 23, 2003
Days to decision	64 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Omi Manufacturing Pty., Ltd.**
Location	Deer Field, IL, US
Contact	DANIEL KAMM
510(k) history	2 submissions · 2 cleared · 2003-2006