FDA 510(k) Premarket Notification

K090309 LAGIS ENDOSCOPIC INSTRUMENTS

CLEARED

Aug 28, 2009
203 days to decision

K090309 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k090309/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Feb 6, 2009
Decision date	Aug 28, 2009
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lagis Enterprises Co, Ltd.**
Location	Houston, TX, US
Contact	JOSEPH J CHANG
510(k) history	2 submissions · 2 cleared · 2009-2015