FDA 510(k) Premarket Notification

K080382 SELLAS

CLEARED

Sep 24, 2008
224 days to decision

K080382 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k080382/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 13, 2008
Decision date	Sep 24, 2008
Days to decision	224 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Dinona Co., Ltd.**
Location	Littleton, CO, US
Contact	Kevin Walls
510(k) history	1 submissions · 1 cleared · 2008-2008