

K162398 CO2 Laser Therapy SystemsJul 6, 2017
314 days to decisionK162398 · Product code: **ONG** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k162398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument With Microbeamfractional Output (ONG)
Date received	Aug 26, 2016
Decision date	Jul 6, 2017
Days to decision	314 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beijing Sincoheren Science and Technology Development Co.
Location	Beijing, CN
Contact	XIN WANG
510(k) history	2 submissions · 2 cleared · 2017-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162398/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 1, 2026