

K220794 10PLNov 10, 2022
237 days to decisionK220794 · Product code: **ONF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220794/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Mar 18, 2022
Decision date	Nov 10, 2022
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tentech Co. , Ltd.
Location	Gangnam-Gu, KR
Contact	Lee Dong Gun
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220794/> 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 May 26, 2026