

K211942 Heating Lumbar Therapy Cushion (Model: AST-622, AST-622B, AST-623, AST-623B)Dec 13, 2021
173 days to decisionK211942 · Product code: **NGX** · Physical Medicine
Source: <https://www.510kdatabase.net/k211942/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Jun 23, 2021
Decision date	Dec 13, 2021
Days to decision	173 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Osto Technology Company Limited
Location	Shenzhen City, Guangdong Province, CN
Contact	Li Yang
510(k) history	7 submissions · 7 cleared · 2014-2022

REGULATORY CONSULTANT

Consulting firm	Guangzhou GLOMED Biological Technology Co., Ltd.
Contact	Cassie Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211942/> 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 25, 2026