

# K200983 Infrared light therapy led facial light therapy mask- Derma plus, Photons Facial Skin Care Machine LED Beauty Mask Therapy Beauty Machine

Jul 14, 2021  
456 days to decision

K200983 · Product code: **OHS** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k200983/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Apr 14, 2020
Decision date	Jul 14, 2021
Days to decision	456 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Ningbo Hesi Electric Co., Ltd.</b>
Location	Ningbo, CN
Contact	Ma LuLu
510(k) history	1 submissions · 1 cleared · 2021-2021

## REGULATORY CONSULTANT

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Consulting firm	<b>Guangzhou Gloomed Biological Technology Co., Ltd.</b>
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)

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k200983/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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