FDA 510(k) Premarket Notification

K220041 HandPICO

CLEARED

May 5, 2022
120 days to decision

K220041 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220041/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 5, 2022
Decision date	May 5, 2022
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Vydence Medical Industria E Comercio Ltda**
Location	Ceat - Sao Carlos/Sp Sao Paulo, BR
Contact	Kathy Maynor
510(k) history	4 submissions · 4 cleared · 2018-2022

REGULATORY CONSULTANT

Consulting firm	**Kathy Maynor**
Contact	Kathy Maynor

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov