

K213247 JETT PLASMA Medical IIMar 14, 2023
530 days to decisionK213247 · Product code: **QVJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k213247/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low Power Electrosurgical Devices For Skin Lesion Destruction (QVJ)
Date received	Sep 30, 2021
Decision date	Mar 14, 2023
Days to decision	530 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Compex, Spol, S.R.O.
Location	Brno, CZ
Contact	Eva Hamplova
510(k) history	2 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Medical Device Academy, Inc.
Contact	Robert V Packard

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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