FDA 510(k) Premarket Notification

K211207 Diacare 7000

CLEARED

Jun 6, 2022
410 days to decision

K211207 · Product code: **PBX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k211207/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Apr 22, 2021
Decision date	Jun 6, 2022
Days to decision	410 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Globus Sport and Health Technologies, LLC**
Location	Miami, FL, US
Contact	Jorge Millan
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Sigma Biomedical**
Contact	Jorge Millan

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