FDA 510(k) Premarket Notification

K232383 iPhysio® System

CLEARED

Mar 4, 2025
574 days to decision

K232383 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k232383/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Aug 8, 2023
Decision date	Mar 4, 2025
Days to decision	574 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Euroteknika**
Location	Montreal, Quebec, CA
Contact	Yoann Delatre
510(k) history	3 submissions · 3 cleared · 2009-2025

REGULATORY CONSULTANT

Consulting firm	**Secure BioMed Evaluations**
Contact	Justin Gracyalny

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