CLEARED

K213022 CEFLA Dental Micromotors: i-MMr, i-MMr L, i-MMs, i-XR3, i-XR3 L, i-XS4, handy POWER, handy POWER LED, implantor LED

May 9, 2022
231 days to decision

K213022 · Product code: **EBW** · Dental
Source: https://www.510kdatabase.net/k213022/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Foot, Handpiece And Cord (EBW)
Date received	Sep 20, 2021
Decision date	May 9, 2022
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cefla S.C.**
Location	Imola (Bo), IT
Contact	Lorenzo Bortolotti
Website	https://www.cefla.com
510(k) history	20 submissions · 20 cleared · 2008-2026

Cefla S.C. is a diversified industrial group based in Imola, Italy. The company operates through multiple business units, including a dedicated Medical Equipment division that develops dental and diagnostic imaging devices. Cefla has maintained a strong FDA 510(k) regulatory record since 2008. The company has received FDA 510(k) clearances from total submissions, with no denied submissions. Its cleared devices span radiology and dental categories, including cone beam computed tomography (CBCT) systems, dental micromotors, and apex locators. The latest clearance was grante...