

K230895 CEFLA Dental Micromotors: i-MMr, i-MMr L, i-MMr L FLUO, i-MMs, i-MMs FLUOApr 1, 2024
367 days to decisionK230895 · Product code: **EBW** · Dental
Source: <https://www.510kdatabase.net/k230895/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Foot, Handpiece And Cord (EBW)
Date received	Mar 31, 2023
Decision date	Apr 1, 2024
Days to decision	367 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	i-XR3, i-XR3 L, i-XR3 L FLUO, i-XS4,

APPLICANT

Company	Cefla S.C.
Location	Imola (Bo), IT
Contact	Daidone Simona
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...