

K983183 GYRO LONG-LIFE, BLACK PEARL ECO, ONDINE & CROMA, PRESTIGE, BORA, AQUILON, MC2, MC3, BASCH, ISOLITE, OPTIMA, US, PLPE, CA, P

Dec 10, 1998
90 days to decision

K983183 · Product code: EFB · Dental
Source: <https://www.510kdatabase.net/k983183/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	Sep 11, 1998
Decision date	Dec 10, 1998
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bien Air USA, Inc.
Location	Irvine, CA, US
Contact	ARTHUR MATEEN
510(k) history	2 submissions · 2 cleared · 1998-1999

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Device record: <https://www.510kdatabase.net/k983183/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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