

K241074 High-speed Air Turbine Handpieces (SCHG01, SCHG03, SCHG18, SCHF19, SCHF22), Dental Low Speed Handpieces including Straight and Geared Angle Handpieces and Air Motors (Straight Handpieces: SCHED05-S, SCHED16-S, SCHED17-S, SCHED24-S, SCHED27-S Geared Angle Handpieces: SCHED05-C, SCHED06-C, SCHED16-C, SCHED17-C, SCHED24-C, SCHED27-C, SCHED29-S, SCHB4, SCHB5, SCHB20, SCHB64 Air Motors: SCHED16-M, SCHED17-M, SCHED24-M, SCHED27-M)

Nov 12, 2024
207 days to decision

K241074 · Product code: EFB · Dental
Source: <https://www.510kdatabase.net/k241074/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	Apr 19, 2024
Decision date	Nov 12, 2024
Days to decision	207 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Foshan Soco Precision Instrument Co., Ltd.
Location	Foshan, CN
Contact	Gou Xiao
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray Wang

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

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Device record: <https://www.510kdatabase.net/k241074/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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