DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 28, 2017

Sawbros Industries Pvt., Ltd.
Dhruv Sawhney
Manager Regulatory
A-68 Sector 2
Noida, Uttar Pradesh 201301
INDIA

Re: K162543
Trade/Device Name: Reverse Pull Adjustable Facemask
Regulation Number: 21 CFR 872.5500
Regulation Name: Extraoral orthodontic headgear
Regulatory Class: Class II
Product Code: DZB
Dated: July 6, 2017
Received: July 25, 2017

Dear Dhruv Sawhney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Ryan -S

for Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162543

Device Name
Reverse Pull Adjustable Facemask

Indications for Use *(Describe)*
Use as a treatment option for Class III malocclusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92.(c)

807.92(a)(1)

Submitter

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807.92(a)(2)

Device Name:

Trade Name	Reverse Pull Adjustable Facemask
Common Name	Orthodontic Facemask, Chin Cup, Adjustable Facemask, Reverse Pull Headgear
Classification Name	Extraoral Orthodontic Headgear
Regulation No.	21CFR872.5500
Classification Code	DZB

807.92(a)(3)

Predicate Device

	Device Name	*510 (k)*	*Company Name*
Primary Predicate	MULTI ADJUSTABLE FACE MASK	K000358	ORTHO TECHNOLOGY

807.92(a)(4)

Device Description

The Reverse Pull Adjustable Facemask is an extra oral device placed on the face of a patient. The subject device is provided assembled; packaged in a plastic heat sealed bag placed in a nylon pouch, to safeguard the integrity of the packaging. The device is provided non(sterile. No prior skin preparation is required to use the device. The skin contacting surfaces may require light cleaning with water between uses, depending on the patient's personal hygiene.

The subject device consists of a vertical main frame, made of 304(grade stainless steel, having adjustable supports for the patient's forehead and chin. The two supports are lined with Ethylene(Vinyl Acetate (EVA) plastic foam for patient comfort. Moreover, the forehead support has two vents

to allow airflow to skin in contact with the support. Two additional EVA pads for forehead and chin supports are included for patient comfort and hygiene.

An elastic capstan crossbar made of 304 grade stainless steel, with an allen screw is present on the vertical main frame between the forehead and chin support. The crossbar is utilized by the Orthodontic practitioner as a means of anchorage support for attaching elastics to intraoral appliances. Elastics or the intraoral appliances are not provided with this device.

Table 1. List of models included within this submission

Model#	Description
426(055RM	Reverse Pull Adjustable Facemask (Blue)
426(056RM	Reverse Pull Adjustable Facemask (Teal)
426(057RM	Reverse Pull Adjustable Facemask (Red)
426(058RM	Reverse Pull Adjustable Facemask (Pearl)
426(050RM	Chin Cup

807.92(a)(5)

Indications for Use

Use as a treatment option for Class III malocclusion.

807.92(a)(6)

Basis for Substantial Equivalence

The Reverse Pull Adjustable Facemask has almost identical components and construction as the predicate device. The similarity in design and construction between the Reverse Pull Adjustable Facemask and the predicate device supports the equivalence of the Reverse Pull Adjustable Facemask for the indicated use as demonstrated in table 2.

Table 2. Comparison of Subject device with Primary Predicate

	Subject Device	***Primary Predicate***
510(K) Number	K162543	K000358
Device Name	Reverse Pull Adjustable Facemask	Multi Adjustable Facemask
Applicant	Sawbros Industries Pvt. Ltd.	Ortho Technology
Indication for Use	Reverse Pull Adjustable Facemask is used as a treatment option for Class III malocclusion.	Multi Adjustable Facemask is used as a treatment option for Class III malocclusion.
Principle of Operation	Extra oral anchorage support for elastics from intra oral appliances.	Extra oral anchorage support for elastics from intra oral appliances.

Anatomical location of use	Face of patient.	Face of patient.
Patient Contact	Forehead and chin	Forehead and chin
Components		
Main Frame Material	304 Stainless Steel	304 Stainless Steel
Main Frame Cross Section	0.146"x0.116"	0.140"x0.115"
Mobilisation Screw on Chin Cup	Allen Screw M3 length 4mm Present	Allen Screw M3 length 4mm Present
Chin Cup Support material	EVA Plastic foam	EVA Plastic foam
Upper/Lower Stop Screw for Chin	Absent	Absent
Chin Cup Mobility	Immobile during use	Immobile during use
Forehead support material	EVA Plastic foam	EVA Plastic foam
Air Vents in Forehead Support	Present	Present
Crossbar Construction	Capstan circular	Capstan circular
Crossbar Material	304 Stainless Steel	ABS Plastic
Protection buttons end of Main frame	Present	Present
Appliance Weight	1.86 oz	1.90 oz
Screw	Allen Screw M3 length 4mm	Allen Screw M3 length 4mm
Time dependant degradation	Low likelihood	Low likelihood
Appearance		

As demonstrated in table 2, Reverse Pull Adjustable Facemask is substantially equivalent to the predicate device in terms of indications for use, material, composition and design.

807.92(b)(1)

Nonclinical Tests Discussion

Performance tests in accordance to ISO 6892(1:2016 for tensile testing of metallic materials at room temperature was conducted on the final finished device configuration as well as the predicate device to determine the equivalence. Biocompatibility was evaluated by preparing a risk assessment as per ISO 14971. The subject device has a similar tensile strength as the predicate and is therefore substantially similar to the predicate.

807.92(b)(2)

Clinical Tests Discussion

No clinical field trials have been conducted with Reverse Pull Adjustable Facemask.

807.92(b)(3)

Conclusion

The Reverse Pull Adjustable Facemask has an equivalent intended use, identical operation and substantially similar technological specifications as the predicate device. Based on the information provided in this premarket notification we conclude that the Reverse Pull Adjustable Facemask is equivalent as the predicate device.