May 1, 2023

WorldWork S.R.L
Daniela Baldissera
Consultant
Via Del Progresso, 47
Montebello, Vicentino 36054
ITALY

Re: K223182
Trade/Device Name: Arial Dental, Mistral Dental Amalgam, World Work Dental Amalgam, BMS Non Gamma 2 Alloy, Flexi Alloy, Hi-S Alloy, WW Dental Amalgam, Hi - Mix, Non Gamma 2 Alloy
Regulation Number: 21 CFR 872.3070
Regulation Name: Dental Amalgam, Mercury, And Amalgam Alloy
Regulatory Class: Class II
Product Code: OIV, EJJ
Dated: February 27, 2023
Received: March 6, 2023

Dear Daniela Baldissera:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223182

Device Name
Arial Dental , Mistral Dental Amalgam
World Work Dental Amalgam, Flexi Alloy, Hi-S Alloy,
BMS Non Gamma 2 Alloy, WW Dental Amalgam, Hi-Mix, Non Gamma 2 Alloy

Indications for Use *(Describe)*
Filling material as a treatment for dental caries

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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K223182

510(k) SUMMARY

Regulatory Correspondent:	World Work Srl Contact person: Daniela Baldissera e-mail: quality@worldwork.it
Submitter of 510(k):	World Work Srl Via del Progresso, 47-36054 Montebello Vicentino (VI). Italy Tel: +39 0444 574297 Fax: +39 0444 370543
Date of Summary:	17th April 2023
Trade/Proprietary Name	**Subject Devices** Arial Dental, Mistral Dental Amalgam World Work Dental Amalgam, Flexi Alloy, Hi-S Alloy, BMS Non Gamma 2 Alloy, WW Dental Amalgam, Hi - Mix, Non Gamma 2 Alloy
Common/Usual Name	Alloy Amalgam
Product Code	EJJ
Regulation	21 CFR872.3070
Classification name:	Alloy, Amalgam
Indications for Use:	Filling material as a treatment for dental caries
Device Description:	The subject devices are a mixture (alloy) of silver and several other metals, used by dentists to make fillings for tooth cavities. Amalgam alloys have been the most commonly used direct restorative filling material for over a 100 years. Note: Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy - Guidance for Industry and FDA Staff was used.
Predicate Device:	K801639 Permite Dental Amalgam Alloy
Substantial Equivalence:	The abovementioned subject devices are substantially equivalent in intended use and technological characteristics to Permite (K801639, SOUTHERN DENTAL INDUSTRIES., INC.) Any difference that exists between our subject devices and the predicate device has no negative effect on safety or effectiveness.

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COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Product name / **Characteristics**	Acceptance criteria ISO 24234	**Subject Devices** Arial Dental , Mistral Dental Amalgam World Work Dental Amalgam, BMS Non Gamma 2 Alloy, Flexi Alloy, Hi-S Alloy, WW Dental Amalgam, Hi - Mix, Non Gamma 2 Alloy	**Predicate Device** Permite Dental Amalgam Alloy	**Differences & Remarks**
510K		K223182	K801639	
Intended use:		Filling material as a treatment for dental caries	Filling material as a treatment for dental caries	None. All products are intended to be used as a filling material in restorative dentistry
Chemical Composition				
Alloy Silver (Ag) CAS 7440-22-4 Tin (Sn) CAS 7440-31-5 Copper(Cu) CAS 7440-50-8 Alloy-mercury Ratio	Ag ≥ 40 Sn ≤ 32 Cu ≤ 30 Zn ≤ 2	Each of the devices is available in 2 composition types (indicated in label) a) Ag 44,5% Sn 30% Cu 25,5% b) Ag70% Sn18% Cu12% The difference between the devices is only in the composition. (High silver and low silver content) 1:1 (Mercury 50%)	Ag 56%, Sn 27.9%, Cu 15.4% In 0.5%, Zn 0.2% The alloy to mercury ratio varies between 1/0.86 and depending on the size and 1/0.96 setting time i.e. 46.2% to 49.5% by weight .mercury	Compositions meet the requirements of ISO 24234
Physical Properties				
Particle shape & size		Admix - spherical and lathe cut 15 µm - 35 µm.	Admix - spherical and lathe cut 15 µm - 35 µm	This parameter is not specified by a technical standard, it depends on the characteristics of the product. Amalgams made from lathe-cut powders or admixed powders tend to resist

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				condensation better than amalgams made entirely from spherical powders
Compressive strength @ 1hr	> 100	171 MPa	260 MPa	Data received is similar and products tested per ISO 24234. All results are within specifications and provide good performance of restoration.
Compressive strength @ 24hr	> 350	443 MPa	500 MPa	
Working times (minutes)		Condense: 2.5 - 5 Carving: 4.5 - 7	Condense: 2.5 - 5 Carving: 5.5 - 7	
Corrosion products ions leached and mercury vapor released during corrosion (ng/cm2 in 4 hrs)		2 (µg/cm2) < 65ng/cm2	2.5 (µg/cm2) < 65ng/cm2	
Creep	Max. 2%	0.5%	0.2%	
Dimensional change	−0,10 to +0,15	0.1	-0.04%	
Trituration time (seconds) High speed Amalgamator for capsule form.		4-8	6 - 8	Trituration time depends on spill size, variations in amalgamator used (type, age, line voltage). This however does not affect the safety and effectiveness of the products.
Presentation forms		Capsules: 1,2 and 3 spill	Capsules: 1,2 ,3 & 5 spill	

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Sterilization & Shelf life	World Work Srl dental amalgams have been marketed in other regions for over 15 years . The subject devices have shown clinical effectiveness and safety as well as stability under defined storage conditions. The components are same as those used in predicate device and other legally marketed dental amalgams. Dental Amalgam alloys are not sterile products
Performance Non Clinical Testing	Performance testing was completed in accordance to ISO 24234 as recommended in the FDA Guidance Document "Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy - Guidance for Industry and FDA Staff . The testing was performed to show that the physical & mechanical properties of subject devices meet requirements . The list of tests carried out are: Package & Capsule contamination Chemical composition and purity of the dental amalgam alloy Large particles in the dental amalgam alloy powder Loss of mass from the capsule during mixing Yield of amalgam from the capsule Consistency of the dental amalgam from capsule to capsule Physical properties (Creep, dimensional change, compressive strength, corrosion) Based on the data received from testing, we conclude that the subject devices are substancially equivalent to Permite Dental Amalgam Alloy (K801639, Southern Dental Industries inc.)
Biocompatibility	A biocompatibility report has been submitted including rationale for end points chosen
Risk	Currently the FDA recommends that high-risk populations as listed below avoid dental amalgam, if possible and appropriate. Children, especially those younger than six People with neurological impairment or kidney dysfunction People who are sensitive to mercury, silver, copper, tin, or zinc Nursing mothers Women who are pregnant or planning to become pregnant The subject devices are for Dental Use Only and to be applied by dental professionals only. The benefits of use far outweigh any risk according to risk analysis carried out.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, World Work SRL concludes that the subject devices:

Arial Dental, Mistral Dental Amalgam , World Work Dental Amalgam, Flexi Alloy, Hi-S Alloy, BMS Non Gamma 2 Alloy, WW Dental Amalgam, Hi - Mix, Non Gamma 2 Alloy

Are safe, effective and substantially equivalent to the predicate device as described herein. They do not introduce new indications for use, have similar technological characteristics and do not introduce new potential hazards or risks.

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