



Food and Drug Administration
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February 11, 2016

AriaBio International, Inc.
% Tali Hazan
Regulatory Consultant
Talmed, Ltd.
Ramot Naftali, Upper Galilee
Ramot Naftali, 13830
ISRAEL

Re: K152555
Trade/Device Name: Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: January 10, 2016
Received: January 13, 2016

Dear Tali Hazan:

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" (21 CFR 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 yours,

 Tina Kiang -
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for Erin I. Keith, M.S.

Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K152555

Device Name
Dental Implant System

Indications for Use (Describe)

Aria Bio's Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Dental Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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 for Aria Bio's
Dental Implant and Abutments**

1. Date Prepared: 07 February 2016

2. 510(k) Owner Name:

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3. Device Name and Classification:

Common/Usual Name: Dental Implant System

Proprietary/Trade name: Dental Implant System

(Implants model names: Fixation, Versatile, Immediate, Solution2, Solution5)

Classification: *Aria Bio Dental Implants and Abutments* have been classified as **Class II** devices under the following classification names:

Regulation Description	Product Code	21 CFR Ref.	Panel
Endosseous dental implant	Primary: DZE Secondary: NHA	872.3640	DAGRID, Dental

4. Predicate Devices:

Aria Bio's Dental Implants and Abutments are substantially equivalent to the following Predicate Devices:

4.1 Primary Predicate Device: AB Dental Implants (by AB Dental Ltd) cleared under K132125; regulation number 872.3640 (Endosseous Dental Implant), product code: DZE (primary) and NHA (secondary).

4.2 Reference Predicate Device: Alpha-Bio Tec Ltd Dental Implant System cleared under K063364; regulation number 872.3640 (Endosseous Dental Implant), product code: DZE.

5. Intended Use/Indications for Use:

Aria Bio's Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Dental Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

6. Device Description:

The Aria Bio Dental Implant System consists of two stage endosseous form dental implants, hexagonal and conical implants and hexagonal and conical abutments; cover screws and healing caps; abutment systems and superstructures and surgical instruments.

The Aria Bio Dental Implant System includes:

Versatile model is a platform switched, tapered implant designed for use in any bone type and is offered with either a deep conical or Morse tapered hex connection. It is available in lengths of 8, 10, 11.5, 13 and 16 mm except for the 4.2 mm diameter which is available in 8, 10, 11.5, 13, 16, 18 and 20, and in diameters of 3.5, 3.75, 4.2, 4.5, 5 and 6 mm. The Versatile implants are constructed of Ti-6AL4V-ELI (Grade 23).

Immediate model is a platform switched root-form implant design. The Immediate suitable for both immediate load applications and insertion into fresh extraction sockets and is offered with either a deep conical or Morse tapered hex connection. It is available in lengths of 8, 10, 11.5, 13, 16 mm except for the 3.5 diameter model which is available in 10, 11.5, 13, 16 mm and in diameters of 3.5, 3.75, 4.2, 4.5, 5 and 6 mm. The immediate implants are constructed of Ti-6AL4V-ELI (Grade 23).

Fixation model is a root form implant is appropriate for both immediate load applications and insertion into fresh extraction sockets. The Fixation is offered with a deep conical or prosthetic connection. The Fixation is available in lengths of 8.5, 10, 11.5, 13, 15, and 18 mm and in diameters of 3.5, 4.3, 5.0 and 6.0 mm. The Fixation implants are constructed of Ti-6AL4V-ELI (Grade 23).

Solution model is equipped with a specially designed, narrow, deep, conical connection and is designed for use in narrow bone volumes. The Solution5 is available in lengths of 10, 11.5, 13, 16 mm with diameter of 3.25 mm. The Solution2 is available with lengths of 8, 10, 11.5, 13, 16 mm and with a diameter of 3.25 mm. The Solution5 and Solution2 differ in that the Solution5 implants have an outer thread like the Immediate implant model, while the Solution2 implants have an outer thread like the Versatile implant model. The Solution implants are constructed of Ti-6AL4V-ELI (Grade 23).

Healing caps are available in 3 platform sizes: normal, narrow and wide and are made of Ti-6AL4V-ELI (Grade 23). The conical connection models are available in narrow, regular and wide platforms with lengths of 2, 3, 4, 5, 6, 7 mm and diameters of 3.0, 3.5 and 4.3 mm. The hex connection models are available in narrow emergence, regular platform with lengths of 2, 3, 4, 5, 6, 7 mm and a diameter of 3.75 mm and wide emergence regular platform with lengths of 3, 4, 5, and 6 mm and a diameter of 3.75 mm.

Temporary abutment is for immediate loading if appropriate and is made of Ti-6AL4V-ELI (Grade 23). It is provided with a plastic cap and is available in 3 hardness levels from the hardest to the softest. The Temporary abutment is available with a conical connection in narrow, regular and wide platforms all with lengths of 1, 2, 3, 4, 5, 6 and 7 mm and diameters of 3.0, 3.5 and 4.3 mm. It is also available with a hex connection regular platform with lengths of 1, 2, 3, 4, 5, 6, 7 mm and a diameter of 3.75 mm.

Temporary abutment plastic caps are for temporary use in conjunction with the temporary abutments for up to 30 days and are constructed of Delrin. They are supplied soft, medium and hard.

Anti Rotation abutments are straight titanium (Ti-6AL4V-ELI (Grade 23)) abutments with hex designed for permanent restoration. The abutments are supplied as regular non-shouldered straight abutments with lengths of 5, 7, 9, 12 and 15 mm with a narrow conical platform of 3.0 mm width, a regular conical platform of 3.5 mm width a regular hex platform of 3.75 mm width and a wide conical platform of 4.3 mm. As a narrow emergence non-shouldered straight abutment with lengths of 5, 7 and 9 mm with a narrow conical platform of 3.0 mm width, a regular conical platform of 3.5 mm width a regular hex platform of 3.75 mm width and a wide conical platform of 4.3 mm. As a wide emergence non shouldered straight abutment with lengths of 9

and 12 mm with a narrow conical platform of 3.0 mm width, a regular conical platform of 3.5 mm width a regular hex platform of 3.75 mm width and a wide conical platform of 4.3 mm.

15° and 25° angular abutment are made of Ti-6AL4V-ELI (Grade 23). 15° abutments are supplied as a conical connection narrow platform with a width of 3.0 mm and lengths of 9, 11 and 13 mm, a conical connection regular platform with a width of 3.5 mm and lengths of 9, 11 and 13 mm and a width of 3.75 mm with a length of 9 mm, a conical connection wide platform with a width of 4.3 mm and lengths of 9, 11 and 13 mm, a hex connection regular platform with a width of 3.75 mm and a length of 9 and 11 mm. 25° abutments are supplied as a conical connection narrow platform with a width of 3.0 mm and lengths of 9, 11 and 13 mm, a conical connection regular platform with a width of 4.3 mm and lengths of 9, 11 and 13 mm, a conical connection wide platform with a width of 3.5 mm and lengths of 9, 11 and 13 mm and , a hex connection regular platform with a width of 3.75 mm and lengths of 9, 11 and 13 mm. 15° and 25° narrow emergence abutments are supplied as a conical connection narrow platform with a width of 3.0 mm and length of 9.0 mm, as a conical connection regular platform with a width of 3.5 mm and length of 9.0 mm, as a conical connection wide platform with a width of 4.3 mm and length of 9.0 mm and as a hex connection regular platform with a width of 3.75 mm and length of 9.0 mm.

Anatomic Straight Abutment are constructed of Ti-6AL4V-ELI (Grade 23). All have a length of 7.5mm and shoulder heights of 1, 2 and 3 mm. They are available in the following configurations: Conical connection, narrow platform 3.0 mm width, Conical connection, regular platform 3.5 mm width, Conical connection, wide platform 4.3 mm width, Hex connection, regular platform 3.75 mm width, Wide emergence, conical connection, narrow platform width 3.0 mm, Wide emergence, conical connection, regular platform width 3.5 mm, Wide emergence, conical connection, wide platform width 4.3 mm, Wide emergence, hex connection, wide platform width 4.3 mm

15°, 25° and 30° Angled Anatomic Abutment with Shoulder, all have a length of 7.5 mm and are constructed of Ti-6AL4V-ELI (Grade 23). They all have shoulder heights of 1, 2 and 3 mm and are available as conical connection, narrow platform width 3.0 mm, conical connection, regular platform width 3.5 mm, conical connection, wide platform width 4.3 mm, hex connection, regular platform width 3.75 mm.

Straight Adaptor are all constructed of Ti-6AL4V-ELI (Grade 23) and are supplied in lengths of 1, 2, 3, 4, 5 and 6 mm in the following models: conical connection, narrow platform diameter 3.0 mm, conical connection, regular platform diameter 3.5 mm, conical connection, wide platform diameter 4.3 mm, hex connection, regular platform diameter 3.75 mm.

Casting Sleeves for Straight Adaptor are available in gold and titanium, all with width of 4.5mm and a length of 10.0 mm. Both gold and titanium are available in the following configurations: Gold sleeve casting adaptor, conical, narrow, Gold sleeve casting adaptor, conical, regular, Gold sleeve casting adaptor, conical, wide, Gold sleeve casting adaptor, hex, regular.

Ball Attachment Abutments are all constructed of Ti-6AL4V-ELI (Grade 23). All provided with lengths of 1, 2, 3, 4, 5 mm and in the following configurations: Conical connection, narrow platform 3.0 mm diameter, Conical connection, regular platform 3.5 mm diameter, Conical connection, wide platform 4.3 mm diameter , Hex connection, regular platform 3.75 mm diameter.

Multi-Unit Abutment are all constructed of Ti-6AL4V-ELI (Grade 23) and are supplied with lengths of 1, 2, 3 and 4 mm. The following configurations are available in both narrow and wide platforms and in hex regular platform: Straight, Conical Connection 18°, Conical Connection 30°, Narrow and Wide Platform.

Cover Screw are all constructed of Ti-6AL4V-ELI (Grade 23) and are supplied with a conical connection as narrow, regular and wide and with a hex connection.

7. Substantial Equivalence:

The proposed Aria Bio Dental Implant System has similar indications for use, technological characteristics, mode of operation and, performance specification as the above identified predicate devices. The proposed device utilizes similar intended use as the predicates and is placed using the same methodology as all of the selected predicate devices. Both the proposed and predicate devices function in the same manner providing support for prosthetic devices in the upper or lower jaw, having similar range of dimensions and basic shape. The specific indications for use for the current device and two predicate devices are shown in the following table:

510(k) Number	K063364 (Reference PD)	K132125 (Primary PD)	K152555 (Proposed)
Device	Alpha-Bio Tec Dental Implant System	A.B. Dental Devices Dental Implants System	Aria Bio Dental Implant System
Indications for Use	<p>The Alpha-Bio Dental Implant System® is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Alpha-Bio Dental Implant System® is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.</p>	<p>A.B.Dental Devices Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. A.B. Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.</p> <p>Two Stage Implants: 12,15,16131. One Stage: 16, 16b, 168. One Stage & One-Piece 3.0 mm diameter implants: 16, 168, 16131, are intended for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants. One stage & One-Piece 2.4 mm diameter implants for temporary use or long term use: 16, 16b, permit immediate splint stability and long term fixation of new or existing crown, bridge and prosthesis. P1 4 Angulated Abutment Adapter is to be used with implant diameter 4.2mm and higher.</p>	<p>Aria Bio's Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, in order to restore the patient's chewing function. The Dental Implant System is indicated also for immediate loading when good primary stability is achieved with appropriate occlusal loading.</p>

Differences that were identified were addressed as follows:

Implants differences –

With the exception of the surface treatment the Aria Bio implants are similar as the two predicate implants. The predicate devices are treated with Calcium Fosfat-Hydroxyapatite while the Aria Bio implants are treated with HA blasting/Double acid etching. The slight difference in the surface treatment methods is not likely to affect the Titanium biocompatibility since both methods are valid and acceptable within the dental industry and biocompatibility was demonstrated by Aria Bio.

Aria Bio products' list also do not include one-piece (one-stage) implant within this submission.

Abutments –

The difference between the Aria Bio abutments and the predicate abutments are in the dimensions offered. These difference are displayed in the following table (Abutments not shown do not differe from the predicate:

Product Description	Aria Bio Product		Predicate Devices:	
	Diameter (mm)	Length (mm)	Diameter (mm)	Length (mm)
			<i>AlphaBio K#063364</i>	
Healing abutment, Narrow Platform, Conical	3.0	2, 3, 4, 5, 6, 7	3.2	3, 5, 7
Healing abutment, Regular Platform, Conical	3.5	2, 3, 4, 5, 6, 7	3.6	3, 5, 7
Healing abutment, Wide Platform Conical	4.3	2, 3, 4, 5, 6, 7	3.8 5.0	3, 5, 7 3, 5, 7
			<i>AB Dental K#132125</i>	
Temporary Abutment, Narrow Platform, Conical	3.0	1, 2, 3, 4, 5, 6, 7	3.75	1, 2, 3, 4, 5, 6, 7
Temporary Abutment, Regular Platform, Conical	3.5	1, 2, 3, 4, 5, 6, 7	3.75	1, 2, 3, 4, 5, 6, 7
Temporary Abutment, Wide Platform, Conical	4.3	1, 2, 3, 4, 5, 6, 7	3.75	1, 2, 3, 4, 5, 6, 7
Temporary Abutment, Regular Platform, Hex	3.75	1, 2, 3, 4, 5, 6, 7	3.75	1, 2, 3, 4, 5, 6, 7
			<i>AB Dental K#132125</i>	
Anti-Rotation Abutment, Regular Non-Shouldered Straight, Narrow, conical	3.0	5, 7, 9, 12, 15	3.75	5, 7, 9, 12, 15
Anti-Rotation Abutment, Regular Non-Shouldered Straight, Regular, conical	3.5	5, 7, 9, 12, 15	3.75	5, 7, 9

Product Description	Aria Bio Product		Predicate Devices:	
	Diameter (mm)	Length (mm)	Diameter (mm)	Length (mm)
Anti-Rotation Abutment, Regular Non-Shouldered Straight, Wide, conical	4.3	5, 7, 9, 12, 15	3.75	7, 9
Anti-Rotation Abutment, Narrow Emergence Non-Shouldered Straight, Narrow, Conical	3.0	5, 7, 9	3.75	5, 7, 9, 12, 15
Anti-Rotation Abutment, Narrow Emergence Non-Shouldered Straight, Regular, Conical	3.5	5, 7, 9	3.75	5, 7, 9
Anti-Rotation Abutment, Narrow Emergence Non-Shouldered Straight, Wide, conical	4.3	5, 7, 9	3.75	7, 9
Anti-Rotation Abutment Wide Emergence Non-Shouldered Straight Abutment, Narrow, Conical	3.0	9, 12	3.75	5, 7, 9, 12, 15
Anti-Rotation Abutment Wide Emergence Non-Shouldered Straight, Regular, conical	3.5	9,12	3.75	5, 7, 9
Anti-Rotation Abutment Wide Emergence Non-Shouldered Straight, Wide, conical	4.3	9,12	3.75	7, 9
Anti-Rotation Abutment, Regular Non-Shouldered Straight, Regular, Hex	3.75	5, 7, 9, 12, 15	3.75	5, 7, 9, 12, 15
Anti-Rotation Abutment, Narrow Emergence Non-Shouldered Straight, Regular, Hex	3.75	5, 7, 9	3.75	5, 7, 9
Anti-Rotation Abutment, Wide Emergence Non-Shouldered Straight, Regular, Hex	3.75	9, 12	3.75	7, 9
			AB Dental K#132125	
15° Angled Anatomic Abutment with Shoulder, Conical Connection, Narrow Platform	3.0	1, 2, 3	3.75	1, 2, 3

Product Description	Aria Bio Product		Predicate Devices:	
	Diameter (mm)	Length (mm)	Diameter (mm)	Length (mm)
15° Angled Anatomic Abutment with Shoulder, Conical Connection, Regular Platform	3.5	1, 2, 3	3.75	1, 2, 3
15° Angled Anatomic Abutment with Shoulder, Conical Connection, Wide Platform	4.3	1, 2, 3	3.75	1, 2, 3
25° Angled Anatomic Abutment with Shoulder, Conical Connection, Narrow Platform	3.0	1, 2, 3	3.75	1, 2, 3
30° Angled Anatomic Abutment with Shoulder, Conical Connection, Narrow Platform	3.0	1		
25° Angled Anatomic Abutment with Shoulder, Conical Connection, Regular Platform	3.5	1, 2, 3	3.75	1, 2, 3
25° Angled Anatomic Abutment with Shoulder, Conical Connection, Wide Platform	4.3	1, 2, 3	3.75	1, 2, 3
			AB Dental K#132125	
Straight Adaptor, Conical Connection, Narrow Platform	3	1, 2, 3, 4, 5	3.75	1, 2, 3, 4, 5
Straight Adaptor, Conical Connection, Regular Platform	3.5	1, 2, 3, 4, 5	3.75	1, 2, 3, 4, 5
Straight Adaptor, Conical Connection, Wide Platform	4.3	1, 2, 3, 4, 5	3.75	1, 2, 3, 4, 5
Straight Adaptor, Hex Connection, Regular Platform	3.75	1, 2, 3, 4, 5	3.75	1, 2, 3, 4, 5
			AB Dental K#132125	
Gold Sleeve Casting Adaptor, Conical, Narrow	4.5	10	4.5	10
Gold Sleeve Casting Adaptor, Conical, Regular	4.5	10	4.5	10
Gold Sleeve Casting Adaptor, Conical, Wide	4.5	10	4.5	10

Product Description	Aria Bio Product		Predicate Devices:	
	Diameter (mm)	Length (mm)	Diameter (mm)	Length (mm)
Titanium Sleeve Casting Adaptor, Conical, Narrow	4.5	10	4.5	10
Titanium Sleeve Casting Adaptor, Conical, Regular	4.5	10	4.5	10
Titanium Sleeve Casting Adaptor, Conical, Wide	4.5	10	4.5	10
			<i>AlphaBio K#063364</i>	
Multi-Unit Abutment:				
Multi-Unit Abutment Straight Adaptor, Conical Connection, Narrow Platform		1, 2, 3, 4		1.6, 2.5, 3.5, 4.5 (Regular platform)
Multi-Unit Abutment 18°, Conical Connection, Narrow Platform		1, 2, 3, 4		2.5, 3.5 (Regular platform)
Multi-Unit Abutment 30°, Conical Connection, Narrow Platform		1, 2, 3, 4		3.5, 4.5 (Regular platform)
Multi-Unit Abutment Straight Adaptor, Conical Connection, Regular Platform		1, 2, 3, 4		1.6, 2.5, 3.5, 4.5 (Regular platform)
Multi-Unit Abutment 18°, Conical Connection, Regular Platform		1, 2, 3, 4		2.5, 3.5 (Regular platform)
Multi-Unit Abutment 30°, Conical Connection, Regular Platform		1, 2, 3, 4		3.5, 4.5 (Regular platform)
Multi-Unit Abutment Straight Adaptor, Conical Connection, Wide Platform		1, 2, 3, 4		1.6, 2.5, 3.5, 4.5 (Regular platform)
Multi-Unit Abutment 18°, Conical Connection, Wide Platform		1, 2, 3, 4		2.5, 3.5 (Regular platform)
Multi-Unit Abutment 30°, Conical Connection, Wide Platform		1, 2, 3, 4		3.5, 4.5 (Regular platform)
Multi-Unit Abutment Straight Adaptor, Hex Connection, Regular Platform		1, 2, 3, 4		1.6, 2.5, 3.5, 4.5 (Regular platform)
Multi-Unit Abutment 18°, Hex Connection, Regular Platform		1, 2, 3, 4		2.5, 3.5 (Regular platform)



Product Description	Aria Bio Product		Predicate Devices:	
	Diameter (mm)	Length (mm)	Diameter (mm)	Length (mm)
Multi-Unit Abutment 30°, Hex Connection, Regular Platform		1, 2, 3, 4		3.5, 4.5 (Regular platform)
			<i>AB Dental K#132125</i>	
Ball Attachment Abutment Conical, Regular Platform	3.5	1, 2, 3, 4, 5, 6	4.1	1, 2, 3, 4, 5, 6
Ball Attachment Abutment Conical, Wide Platform	4.3	1, 2, 3, 4, 5, 6	4.1	1, 2, 3, 4, 5, 6
Ball Attachment Abutment Hex, Regular Platform	3.75	1, 2, 3, 4, 5, 6	4.1	1, 2, 3, 4, 5, 6

As can be shown in the comparison table, all the abutments (Aria Bio Dental, Alpha-Bio, AB Dental), consist of many variations which are basically very similar to each other. Any differences between the dimensions of the predicates and the predicate abutments fall well within the dimensions of abutments widely used in the dental field. One abutment angulation of Aria Bio Angled Anatomic Abutment 30° exceeds the predicate maximal angle 25°, yet this difference was evaluated through performance data (fatigue) with successful results. Therefore it was concluded that the dimensional differences do not affect the device substantial equivalency.

In the light of the above, we believe that the overall evaluation of similarities and differences between our device and the selected predicate devices, showed that substantial equivalency of our device with its predicate devices was demonstrated.

8. Performance Testing:

A series of performance tests and evaluations were performed to demonstrate that Aria Bio's Dental Implant System does not raise any new issues that may affect its substantial equivalency with its predicate devices. These evaluations include fatigue (ISO 14801), surface analysis by SEM/EDS and XPS, biocompatibility in accordance with ISO 10993-1, sterilization validation (ISO 11137-2, AAMI TIR 33, ISO 17665-1) and shelf life validation (ISO 11607-1) in order to assure maintaining of SAL 10^{-6} along the shelf life.

All results are supporting Aria Bio's labeling claims in order to establish substantial equivalency.

9. Summary and Conclusion:

We believe that Aria Bio Dental Implants products, which are the subject of this 510(k) submission, are substantially equivalent to the predicate devices cited above. The device constitutes a reliable medical device, meeting all declared requirements of its intended use and the device does not introduce new risks to patients when used as intended.