

510(k) Premarket Notification

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Device Classification Name	powder, porcelain
510(k) Number	K192231
Device Name	Dental Glass Ceramics Blocks
Applicant	Aidite (Qinhuangdao) Technology Co., Ltd. No.9 Dushan Road,Economic And Technological Development Zone Qinhuangdao, CN 066000
Applicant Contact	Zhang Wei
Correspondent	Shenzhen Joyantech Consulting Co., Ltd NO. 55 Shizhou Middle Road , Nanshan District Shenzhen, CN 05755
Correspondent Contact	Christy Young
Regulation Number	972.6660
Classification Product Code	E1H
Date Received	08/16/2019
Decision Date	07/08/2020
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Dental
510k Review Panel	Dental
Summary	Summary
Type	Traditional
Reviewed by Third Party	No
Combination Product	No

Page Last Updated: 09/18/2023

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EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60144008 0001

Report No.: 17047780 009

Manufacturer: Aidite (Qinhuangdao) Technology
Co., Ltd.
No. 9 Dushan Road, Economic And
Technological Development Zone
Qinhuangdao City
066004 Hebei
China

Products:

- Dental Zirconia Ceramics
- Dental Glass Ceramics
- Coloring Liquid Specializeds for Aidite Zirconia Material
- Porcelain Powder
- PMMA Blocks for Dental Use

Replaces Approval, Registration No.: HD 60139224 0001

Expiry Date: 2024-05-27

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-12-02

Date: 2019-12-02



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

[Product advantage »



Aizir represents Aidite's most advanced R&D and production lever integrating several patented technologies in one disc, meanwhile meeting the full range of indications. It has larger systematic processing, a wider sintering temperature range, and a increased stable three-dimensional gradient effect.

Aizir will uphold the vision of "making people healthier and more beautiful" and redefine all-ceramic prosthetic materials.



16 years

Aidite has 16 years of experience in the development and production of zirconia, with stable material performance.

2h

On the basis of realizing rapid sintering, Aizir is compatible with many kinds of Aidite zirconia materials (such as SHT-PC, SHTM) to achieve simultaneous sintering of multiple materials.

1510-1570°C

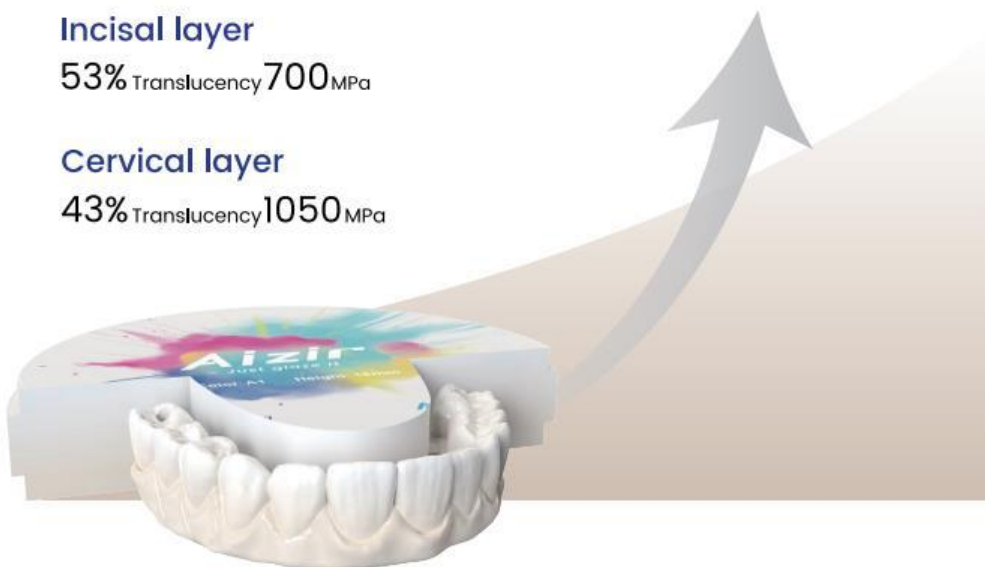
Aizir has an ultra-wide sintering temperature range, giving a perfect bionic aesthetic effect at different temperatures.

Incisal layer

53% Translucency 700MPa

Cervical layer

43% Translucency 1050MPa

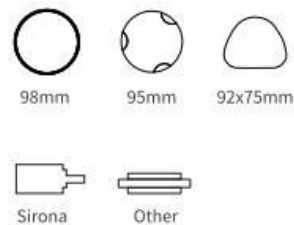


Shade and dimension »



Parameters and application systems »

Color	Vita 16 colors/OM1/OM2/OM3
Aesthetic	Super high translucency
Sintered density	$\geq 6.0\text{g/cm}^3$
Bending strength	Cervical part 1050MPa
Fracture toughness	5Mpa $\text{m}^{0.5}$
Hardness (HV10)	1250



Indications »



Digital work flow »

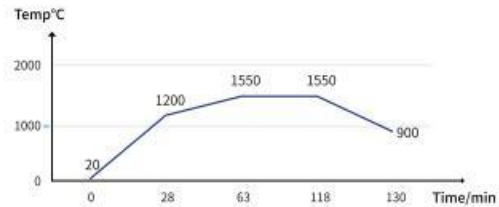
Aizir is one incredible material, which can be used in the above systems, but it is also part of an entire digital workflow. From the intraoral scan to the final restoration, Aidite have validated work-flows with equipment and material for the whole process. Can be achieved faster production time and higher quality with Aizir, take advantages of our service full technical and engineer support, through our dealers and ourselves 7days 24hours never stop worldwide. With Aizir, you are not just purchasing any ordinary zirconia disc, but investing in a part of a wider dedicated system, benefiting the whole dental team and their patients. Dentists will definitely need it once they find out how different it is.



[Sintering curve »

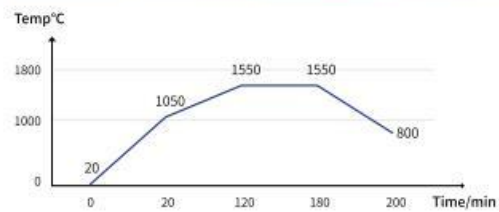
Single crowns & Bridges ≤ 3 unit (2h)

Start temp	Phase 1 heating rate	Phase 1 Maximum temp	Phase 2 heating rate	Phase 2 Maximum temp	Holding time	Cooling rate	Cooling to
20°C	43°C/min	1200°C	10°C/min	1550°C	55min	55°C/min	900°C



Bridges 4-6 unit (3.4h)

Start temp	Phase 1 heating rate	Phase 1 Maximum temp	Phase 2 heating rate	Phase 2 Maximum temp	Holding time	Cooling rate	Cooling to
20°C	51.5°C/min	1050°C	5°C/min	1550°C	60min	37.5°C/min	800°C



Bridges ≥ 7 unit (11.5h)

Start temp	Phase 1 heating rate	Phase 1 Maximum temp	Holding time	Phase 2 heating rate	Phase 2 Maximum temp	Holding time	Cooling rate	Cooling to
20°C	5°C/min	900°C	30min	3°C/min	1530°C	120min	8°C/min	300°C

