December 13, 2019

DentsCare LTDA
% Rodrigo Abreu
Regulatory Specialist
United Regulatory LLC
12343 NW 25th St
Coral Springs, Florida 33065

Re: K183424
Trade/Device Name: Ambar, Ambar APS, Ambar Universal APS
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: November 11, 2019
Received: November 13, 2019

Dear Rodrigo Abreu:

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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183424

Device Name
Ambar APS and Ambar Universal APS

Indications for Use *(Describe)*
- All classes of direct restoration with composites (class I, II, III, IV and V);
- Adhesive luting (in addition to resin cement) of prosthetic pieces (post/cores, crowns, onlays/inlays, veneers etc.) made of fiberglass, ceromer, ceramic, resin and metal;
- Adhesive repairs in ceramic and composites.
*Only for Ambar Universal APS: Use as metallic or ceramic primer.

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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Section 5
510(k) SUMMARY

Revision date: December 12, 2019

A) Submitter's Name: DENTSCARE LTDA

Owner / Operator Registration Number: 3007210751

Manufacture Registration Number: 3007210751

B) Address: AV. EDGAR NELSON MEISTER, 474, JOINVILLE, SANTA CATARINA 89219-501 BRAZIL

C) Phone and Fax Numbers

Phone: +55 (47) 34416131

D) Contact Person:

Roberta Uyara

Tel.: +55 (47) 34416131

E) Preparation Date: December 12, 2019

F) Classification Name: Resin tooth bonding agent

Common / Usual Name: Tooth Bonding Adhesive

Proprietary Name: Ambar APS and Ambar Universal APS

Product Code: KLE

Class: Class II

Regulation: 21 CFR 872.3200

G) Device Description

Ambar APS

Ambar APS is a light-curing 5th generation adhesive (two-step adhesive, total etch technique) for bonding restorative materials to dental tissue (enamel and/ or dentin). As the primer and the bonding agent are combined in a single bottle, acid etching is the only previous step needed before applying the adhesive to dentin and enamel.

Ambar Universal APS

Ambar Universal APS is a single flask self-etch light-curing adhesive system (Seventh Generation) responsible for the union between tooth structure (enamel and dentin) and restorative materials. The primer and bonding agent are combined in a single flask. Prior use of acid etchant is optional on both tooth´s enamel and dentin, it can be used, therefore, in three ways: self-etch, selective-etch and total-etch.

H) Substantial Equivalence:

The Ambar APS and Ambar Universal APS are equivalent with the following products:

510(k) Number	Model	Company
K962785 (primary predicate)	3M Dent System (Single Bond 2)	3M COMPANY

I) Reference Devices:

510(k) Number	Model	Company
K110302	Adhesive EXL 759 (Single Bond Universal)	3M COMPANY
K133318	Adhese Universal (Tetric – N – Bond Universal)	Ivoclar

J) Indications for Use:

Indication for Use Comparison			
Ambar APS and Ambar Universal APS **Dentscare**	**3M Dent System (Single Bond 2)** **3M** (primary predicate)	**Adhesive EXL 759 (Single Bond Universal)** **3M**	**Adhese Universal (Tetric – N – Bond Universal)** **Ivoclar**
- All classes of direct restoration with composites (class I, II, III, IV and V); - Adhesive luting (in addition to resin cement) of prosthetic pieces (post/cores, crowns, onlays/inlays, veneers etc.) made of fiberglass, ceromer, ceramic, resin and metal; - Adhesive repairs in ceramic and composites. *Only for Ambar Universal APS: Use as metallic or ceramic primer.	Direct light-cured composite/compomer restorations	All classes of fillings (according to Black) with light-curing composite or compomer filling materials	Direct-placed light-curing composite and compomer restorations
	Porcelain veneers (when used with RelyX™ Veneer Cement) Crown & bridge, inlay/onlay, bonding amalgam (when used with RelyX™ ARC Adhesive Resin Cement)	Cementation of indirect restorations (inlays, onlays, crowns, bridges, veneers) of composite, compomer, ceramic, and metal when combined with Suglue-10 Adhesive Resin Cement, manufactured by 3M ESPE Cementation of veneers when combined with RelyX Veneer Cement, manufactured by 3M ESPE Bonding of core build-ups made of light-curing composite or core build-up materials Bonding of dual-cure cements and core build-up materials and self-cure composites when combined with Activator EXL 760	Direct-placed core build-ups with light-, self- and dual-curing composites Adhesive cementation of indirect restorations with light- and dual-curing luting composites
	Porcelain / composite repair	Repair of composite or compomer fillings Intraoral repair of composite restorations, porcelain fused to metal, and all-ceramic restorations without extra primer	Repair of fractured composite and compomer restorations.

	Not indicated	Surface treatment of porcelain, ceramics (including glass ceramics, zirconia and alumina), metal and composite	Not indicated
	Root surface desensitization	Root surface desensitization	Desensitization of hypersensitive cervical areas
	Not indicated	Sealing of cavities prior to cementation of amalgamate restorations Sealing of cavities and preparation of tooth stumps prior to temporary cementation of indirect restorations	Sealing of prepared tooth surfaces before temporary / permanent cementation of indirect restorations
	Not indicated	Bonding of fissure sealants Protective varnish for glass ionomer fillings	Not indicated

Discussion: The subject devices are adhesive systems that offer the dental professional a wide range of applications. The Ambar APS and Ambar Universal APS are substantially equivalent to the predicate device (Single Bond 2) and the reference devices (Single Bond Universal and Tetric – N – Bond Universal) above in that all are intended to be used as a 21 CFR 872.3200 resin tooth bonding agent. The subject devices are substantially equivalent to Single Bond 2 in terms of indications. Regarding the claim "Use as metallic or ceramic primer", the Ambar Universal APS it similar to the reference predicate, Single Bond Universal, that indicates the use for "Surface treatment of porcelain, ceramics (including glass ceramics, zirconia and alumina), metal and composite."

K) Technological Characteristics Comparison:

The predicate device used to establish substantial equivalence for the Ambar APS and Ambar Universal APS device is outlined below. This section of this submission will provide a comparison of design, materials, and technical specifications of the Ambar APS and Ambar Universal APS to each of the predicate devices stratified by functional modality.

Device Manufacturer and Common Name	**Ambar APS and Ambar Universal APS** **Dentscare**	**3M Dent System (Single Bond 2)** **3M** (primary predicate)	**Adhesive EXL 759 (Single Bond Universal)** **3M**	**Adhese Universal (Tetric – N – Bond Universal)** **3M**
510k #	K183424	K962785	K110302	K133318
Classification	Class II	Class II	Class II	Class II
Regulation #	21 CFR 872.3200	21 CFR 872.3200	21 CFR 872.3200	21 CFR 872.3200
Product Code	KLE	KLE	KLE	KLE, LBH
Classification Name	Resin tooth bonding agent	Resin tooth bonding agent	Resin tooth bonding agent	Resin tooth bonding agent
Patient Population	No restriction, it can be applied to general population	No restriction, it can be applied to general population	No restriction, it can be applied to general population	No restriction, it can be applied to general population
Prescription Use	RX only	RX only	RX only	RX only
Environment	Dental prosthetics and authorized laboratories and clinics. Must be stored in temperatures from 5° to 30°C / 41° to 86°F.	Dental prosthetics and authorized laboratories and clinics. It can be stored at room temperature.	Dental prosthetics and authorized laboratories and clinics. It can be stored at room temperature.	Dental prosthetics and authorized laboratories and clinics. Store conditions not found.

Applicable Standards	ISO 29022; ISO 10993.	ISO 29022; ISO 10993.	ISO 29022; ISO 10993.	ISO 29022; ISO 10993.
Composition	MDP, methacrylate monomers, photo initiators, co-initiators, stabilizers, Inert Load (Silica particles) and Vehicle (ethanol). *Only in Ambar Universal APS: water and surfactant.	Dimethacrylatere sins, HEMA, ethanol, water, photoinitiator system and filler.	MDP, Dimethacrylate resins, HEMA, ethanol, water, photoinitiator system, filler and silane.	Methacrylates, Water, Ethanol, Highly dispersed silicon dioxide, Initiators and Stabilisers.
Device Sterilization	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Indication of Use	- All classes of direct restoration with composites (class I, II, III, IV and V); - Adhesive luting (in addition to resin cement) of prosthetic pieces (post/cores, crowns, onlays/inlays, veneers etc.) made of fiberglass, ceromer, ceramic, resin and metal; - Adhesive repairs in	3M™ ESPE™ Adper™ Single Bond 2 Adhesive is indicated for use in the following types of restorations. - Direct light-cured composite/comp omer restorations - Root surface desensitization -Porcelain / composite repair - Porcelain veneers (when used with RelyX™ Veneer Cement)	- All classes of fillings (according to Black) with light-curing composite or compomer filling materials - Cementation of indirect restorations (inlays, onlays, crowns, bridges, veneers) of composite, compomer, ceramic, and metal when combined with Suglue-10 Adhesive Resin Cement, manufactured by 3M ESPE	- Direct-placed light-curing composite and compomer restorations. - Direct-placed core build-ups with light-, self- and dual-curing composites. - Repair of fractured composite and compomer restorations. - Adhesive cementation of indirect restorations

	ceramic and composites. *Only for Ambar Universal APS: Use as metallic or ceramic primer.	- Crown & bridge, inlay/onlay, bonding amalgam (when used with RelyX™ ARC Adhesive Resin Cement)	- Cementation of veneers when combined with RelyX Veneer Cement, manufactured by 3M ESPE - Bonding of core build-ups made of light-curing composite or core build-up materials - Bonding of dual-cure cements and core build-up materials and self-cure composites when combined with Activator EXL 760 - Repair of composite or compomer fillings - Intraoral repair of composite restorations, porcelain fused to metal, and all-ceramic restorations without extra primer - Root surface desensitization - Sealing of cavities prior to cementation of amalgamate restorations - Sealing of cavities and preparation of tooth stumps prior to temporary	with light- and dual-curing luting composites. - Sealing of prepared tooth surfaces before temporary / permanent cementation of indirect restorations. - Desensitization of hypersensitive cervical areas.

			cementation of indirect restorations - Bonding of fissure sealants - Protective varnish for glass ionomer fillings - Surface treatment of porcelain, ceramics (including glass ceramics, zirconia and alumina), metal and composite.	
How the device achieves its intended purpose	Adhesive Material is a light-curing, single-component dental adhesive for direct and indirect bonding procedures and etching techniques. With total etch adhesives the mineral phase of enamel and dentin is superficially demineralized by an acidic agent (if necessary) in a separate step prior to application of the adhesive. The acid used is typically	Adhesive Material is a light-curing, single-component dental adhesive for direct and indirect bonding procedures and etching techniques. With total etch adhesives the mineral phase of enamel and dentin is superficially demineralized by an acidic agent (if necessary) in a separate step prior to application of the adhesive. The acid used is typically phosphoric acid 35-37%.	Adhesive Material is a light-curing, single-component dental adhesive for direct and indirect bonding procedures and etching techniques. With total etch adhesives the mineral phase of enamel and dentin is superficially demineralized by an acidic agent (if necessary) in a separate step prior to application of the adhesive. The acid used is typically	Adhesive Material is a light-curing, single-component dental adhesive for direct and indirect bonding procedures and etching techniques. With total etch adhesives the mineral phase of enamel and dentin is superficially demineralized by an acidic agent (if necessary) in a separate step prior to application of the adhesive. The acid used is typically

	phosphoric acid 35-37%.		phosphoric acid 35-37%.	phosphoric acid 35-37%.
Side effects:	The adhesive can cause sensitization reactions in patients who are sensitive to any components of the formula. In this case, the material should not be used.	The adhesive can cause sensitization reactions in patients who are sensitive to any components of the formula. In this case, the material should not be used.	The adhesive can cause sensitization reactions in patients who are sensitive to any components of the formula. In this case, the material should not be used.	The adhesive can cause sensitization reactions in patients who are sensitive to any components of the formula. In this case, the material should not be used.
Primary Package Container:	Vial	Unit dose or vial	Unit dose or vial	VivaPen® and Vial
Shelf life	Up to 3 years	Up to 3 years	2 years	Not found
Claims on product performance and safety	Is a light-curing adhesive for bonding restorative materials to dental tissue (enamel and/or dentin).	Is a light-curing adhesive for bonding restorative materials to dental tissue (enamel and/or dentin).	Is a light-curing adhesive for bonding restorative materials to dental tissue (enamel and/or dentin).	Is a light-curing adhesive for bonding restorative materials to dental tissue (enamel and/or dentin).
Use the same materials or substances in contact with the same human tissues or body fluids?	YES	YES	YES	YES
Is the product in compliance to EN ISO 10993?	YES	YES	YES	YES

Tissues	Enamel and Dentin	Enamel and Dentin	Enamel and Dentin	Enamel and Dentin
Reusable	NO	NO	NO	NO
Duration	Permanent	Permanent	Permanent	Permanent
Part of body	Oral, tooth	Oral, tooth	Oral, tooth	Oral, tooth
Is it used for the same clinical condition?	YES	YES	YES	YES
Is it used at the same site in the body?	YES	YES	YES	YES
Is it used in a similar population?	YES	YES	YES	YES
Is it used for the same intended purpose?	YES	YES	YES	YES
Is not foreseen to deliver significantly different performances ?	NO	NO	NO	NO
Is it similar conditions of use?	YES	YES	YES	YES
Is it similar specifications and properties	YES	YES	YES	YES
Is it similar principles of operation?	YES	YES	YES	YES

Adhesive Strength (MPa)	Ambar APS 38,61 ± 1,68 Ambar Universal APS 38,02 ± 3,33	26,20 ± 2,19	34,47 ± 3,34	33,27 ± 3,91
Conversion rate	Ambar APS 53,8 ± 0,5 Ambar Universal APS 55,80 ± 0,5	43,5 ± 1,3	55,60 ± 0,5	45,07 ± 0,6
Shear bond strength (MPa)	Ambar APS 22,21 ± 2,33 Ambar Universal APS 16,30 ± 1,67	20,06 ± 2,52	16,97 ± 1,83	11,91 ± 1,39
pH	Ambar APS 3,16 ± 0,02 Ambar Universal APS 2,97 ± 0,04	4,69 ± 0,03	3,28 ± 0,19	Not performed
Viscosity (mPa.s)	Ambar APS 81,33 ± 2,05 Ambar Universal APS 99,20 ± 0,40	Not performed	Not performed	Not performed
Water sorption (µg/mm³)	Ambar APS 140,80 ± 1,60 Ambar Universal APS 145,53 ± 3,12	150,76 ± 2,26	148,38 ± 2,28	Not performed
Water solubility (µg/mm³)	Ambar APS 64,61 ± 1,86 Ambar Universal APS 64,71 ± 1,59	63,29 ± 2,59	71,24 ± 5,54	Not performed

Discussion:

The subject device is similar to the predicate devices in that they are all dental adhesives for promoting union between tooth structure (enamel and dentin) and restorative materials.

Despite differences in results, the subject device demonstrates substantial equivalence to the declared predicates, since all products meet ISO 29022 and the results match

the requirements of this International Standard and it does not affect the substantial equivalence.

- Adhesive Strength: The average of the results of the adhesive under analysis is ≥ the average of the internationally renowned brand analyzed in this study.

The bond tensile strength exhibits slightly higher values than shear bond strength. Although there is no minimum tensile bond strength value, 20 MPa or more has been proposed as a reasonable value and a goal to be achieved.

By the results obtained, all the adhesives analyzed presented satisfactory results, with slightly higher values obtained by Dentscare adhesives.

The performance of Ambar APS and Ambar Universal APS satisfactorily met the requirements to support substantial equivalence to the predicate.

- Conversion rate: The average of the results of the adhesive under analysis is ≥ the average of the internationally renowned brand analyzed in this study.

The dental compounds basically consist of a mixture of monomers, filler particles, photoinitiator system, inhibitors and dyes. The monomers have methacrylic groups with the carbon double bond, which are photoactivated, form along several polymer chains. The amount of monomers which are converted into polymers represent the major part of the final product, having a lower volume and a smaller amount of free monomers which can be leachable. An analysis of the volume of data is done by analyzing the amount of duplications that have been disrupted, indicating an expression of polymer chains. The higher the conversation rate values, better the results and efficacy of the final product.

By the results obtained, Ambar APS and Ambar Universal APS have presented the highest values, obtaining a higher efficiency of the final product when compared to the predicate. Thus, the results support substantial equivalence to the predicate.

- Shear bond strength: The average of the results of the adhesive under analysis is ≥ the average of the internationally renowned brands analyzed in this study.

The evaluation of the bonding efficiency between an adhesive and the dentin region is usually analyzed by bond strength between bonded specimens in shear or traction until fracture occurs. There is a wide variability of values (deviation) related to several factors such as water content in the dentin, cleaning of the "Smear Layer", orientation of the dentinal tubules.

The enamel structure has a high content of inorganic material (mineral hydroxyapatite) and low amount of organic material such as collagen, thus presenting a lower water content and facilitating adhesive bonding. However in dentine the amount of organic material is higher and, therefore, the humidity is also higher. As the restorative material is hydrophobic and the dentin is hydrophilic, the adhesive system has to be such that it can match both materials, thus, it must have an amphiphilic characteristic.

In summary, the higher the shear bond values, generally for bonding to the enamel, and bonding by traction, generally for adhesion to the dentin structure, the greater the effectiveness of the adhesive system.

The shear bond strength is one of the indicative of adhesive performance, indicating the shear strength between the tooth / adhesive / restorative interface. In enamel indicates the union effectiveness of an orthodontic cement, for example.

The higher the shear strength or tensile strength values, the greater the effectiveness of the product.

- pH: The pH test is not contemplated in standards for adhesives, however, it is known that 7th generation adhesives must have low hydrogen potential, thus performing the role of acid conditioning.

The average of the results for pH of the adhesive under analysis demonstrate that the subject devices have lower hydrogen potential than the average of the internationally renowned brands analyzed in this study.

- Viscosity: The viscosity property is not contemplated in regulations for adhesives. This aspect does not have impact the in the performance of the product. For this reason, the predicate devices do not refer to viscosity of the product as a quality aspect.

- Water sorption and Water solubility: The results show that the subject devices presented Sorption and Solubility similar to the competing adhesives under analysis. There is no specific standard for sorption and solubility testing on adhesives, so we follow the testing methodology established in ISO 4049 and as an approval criterion we define that the results of our adhesives should be better or statistically equal to competitors of recognized quality on market. ISO 4049 reference values have not been taken into account, assuming that the adhesive class is not covered by this standard.

Conclusion: From the results obtained, the subject devices, Ambar APS and Ambar Universal APS demonstrate equivalent indications for use, shelf life, physical, technical and mechanical properties.

L) Applicable Standards:

In order to meet international requirements the device Ambar APS and Ambar Universal APS was developed, as well produced in compliance with recognized international regulations and standards for the medical device industry.

ISO 29022 - Dentistry – Adhesion – Notched edge shear bond strength test
ISO 10993-1 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ENISO 10993-1:2009)
ISO 10993-3 - Biological Evaluation of Medical Devices - Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity.
ISO 10993-5 - Biological Evaluation of Medical Devices - Tests for In vitro Cytotoxicity.
ISO 10993-10 - Biological Evaluation of Medical Device – Tests for Irritation and Skin Sensitization.
ISO 10993-11 - Biological Evaluation of Medical Devices - Tests for Systemic Toxicity.

Conclusion:

Based on compliance with the international standard and regulation mentioned above, the device Ambar APS and Ambar Universal APS demonstrate substantial equivalence to the predicates.

M) Non-clinical Testing:

In order to study the performance of the product, pre-clinical tests were performed according to the table below, for details about test results please see attachment 01.

Test	Specification	Results
Adhesive Strength Testing on Dental Tissue.	A comparative analysis will be carried out between commercial adhesives of internationally recognized quality and the adhesive under analysis. It is defined that the acceptance criterion for this test, if the adhesive under study has a mean ≥ than the competing adhesives analyzed.	The average of the results of the adhesive under analysis is ≥ the average of the internationally renowned brands analysed in this study. Ambar APS: 38,61 ± 1,68 (MPa) Ambar Universal APS: 38,02 ± 3,33 (MPa) Single Bond 2 (3M - Espe): 26,20 ± 2,19 (MPa) Single Bond Universal: 34,47 ± 3,34 (MPa) Tetric – N – Bond Universal: 33,27 ± 3,91 (MPa)
Test for determining the degree of conversion (gc)	A comparative analysis will be carried out between commercial adhesives of internationally recognized quality and the adhesive under analysis. It is defined that the acceptance criterion for this test is if the adhesive under study has a mean ≥ than the competing adhesives analyzed.	The average of the results of the adhesive under analysis is ≥ the average of the internationally renowned brands analysed in this study. Ambar APS: 53,8 ± 0,5 Ambar Universal APS: 55,80 ± 0,5 Single Bond 2 (3M - Espe): 43,5 ± 1,3 Single Bond Universal: 55,60 ± 0,5 Tetric – N – Bond Universal: 45,07 ± 0,6
Test of Shear bond strength (ISO 29022: 2013)	The ISO 29022: 2013 standard does not quantify acceptable and non-acceptable values, so a comparative analysis will be carried out between internationally recognized quality commercial adhesives and the adhesive under analysis. It is defined that the acceptance criterion for this test, if the adhesive under study has a mean ≥ than the competing adhesives analyzed.	The average of the results of the adhesive under analysis is ≥ the average of the internationally renowned brands analysed in this study. Ambar APS: 22,21 ± 2,33 (MPa) Ambar Universal APS: 16,30 ± 1,67 (MPa) Single Bond 2 (3M - Espe): 20,06 ± 2,52 (MPa) Single Bond Universal: 16,97 ± 1,83 (MPa) Tetric – N – Bond Universal: 11,91 ± 1,39 (MPa)
pH	A comparative analysis will be carried out between commercial adhesives of internationally recognized quality and the adhesive under analysis. It is defined that the acceptance criterion for this test, if the adhesive has low hydrogen potential as competing adhesives analyzed.	The average of the results for pH of the adhesive under analysis demonstrate that the subject devices have lower hydrogen potential than the average of the internationally renowned brands analyzed in this study. Ambar APS: 3,16 ± 0,02 Ambar Universal APS: 2,97 ± 0,04 Single Bond 2 (3M - Espe): 4,69 ± 0,03 Single Bond Universal (3M - Espe): 3,28 ± 0,19
Viscosity	Test conducted to attend the FDA requirement, it is no contemplated in regulations for adhesives. However, they have been on the market since 03/2017 (Ambar APS) and 12/2017 (Ambar Universal APS) with no claims regarding viscosity or stickiness, therefore, we can state that its viscosity is in accordance with the desired application.	Ambar APS: 81,33 ± 2,05 mPa.s Ambar Universal APS: 99,20 ± 0,40 mPa.s
Water sorption	There is no specific standard for sorption and solubility testing on adhesives, so we follow the testing methodology established in ISO 4049 and as an approval criterion we	The results show that the subject devices presented Sorption and Solubility similar to the competing adhesives under analysis. Ambar APS: 140,80 ± 1,60 µg/mm³

	define that the results of our adhesives should be better or statistically equal to competitors of recognized quality on market.	Ambar Universal APS: 145,53 ± 3,12 µg/mm³ Single Bond 2 (3M - Espe): 150,76 ± 2,26 µg/mm³ Single Bond Universal: 148,38 ± 2,28 µg/mm³
Water solubility	There is no specific standard for sorption and solubility testing on adhesives, so we follow the testing methodology established in ISO 4049 and as an approval criterion we define that the results of our adhesives should be better or statistically equal to competitors of recognized quality on market.	The results show that the subject devices presented Sorption and Solubility similar to the competing adhesives under analysis. Ambar APS: 64,61 ± 1,86 µg/mm³ Ambar Universal APS: 64,71 ± 1,59 µg/mm³ Single Bond 2 (3M - Espe): 63,29 ± 2,59 µg/mm³ Single Bond Universal: 71,24 ± 5,54 µg/mm³
Accelerated Stability Studies	Study created to accelerate the possible chemical degradation and/or physical changes of the product in forced conditions of storage.	Ambar APS: Considering the results observed at the end of the 477 days of aging test, it is concluded that the product can have its shelf life estimated at 3 years in the storage condition of 30° C. Ambar Universal APS: Considering the results observed at the end of the 225 days of aging test, it is concluded that the product can have its shelf life estimated at 2 years in the storage condition of 25° C.
Evaluation Report of Long-Term Stability (Shelf)	Study designed to verify the physical and chemical characteristics of the product during the expected shelf life. The results are used to confirm the expiration date and storage conditions.	Ambar APS: Considering the results observed at the end of the 36 months of the long-term test (shelf), the shelf life of 3 years in the storage condition of 30°C for the product can be confirmed. Ambar Universal APS: Considering the results observed at the end of the 24 months of the long-term test (shelf), the shelf life of 2 years in the storage condition of 30°C for the product can be confirmed.
Transport Evaluation	Study designed to verify the physical and chemical characteristics of the product during transport.	According to Norm ND7000046 (determination of expiry date and storage conditions of products), the product can be transported at temperatures between 50ºC and -5ºC.