K102874

510(k) SUMMARY
(as required by 807.92(c))

MAR 2 8 2011

Regulatory Correspondent:	Regulatory and Marketing Services Inc 962 Allegro Lane Apollo Beach, FL, 334570 Arthur Ward award@ajwtech.com 813-645-2855 813-677-4787
Submitter of 510(k):	New Stetic Carrera 33, No. 50-09 Guarne, Antioquia, Colombia Edna Cecilia Gil EcGil@newstetic.com
Date of Summary:	9/1/2010
Trade/Proprietary Name:	New Stetic Acrylics New Stetic Denture Base Resins
Classification Name:	Resin, Denture, Relining, Repairing, Rebasing
Product Code:	EBI
Intended Use:	The intended use of New Stetic® Acrylics is for the repair or fabrication of the denture base.
Device Description:	The product is a denture system consisting of monomer and polymer powder and liquid components.
Predicate Device:	K970522 – Myersons Economy Denture Base Material.
Substantial Equivalence:	New Stetic claims the proposed devices to be substantially equivalent to the devices previously cleared by FDA in K970522. New Stetic claims this equivalence because the proposed devices have an

	equivalent intended use, manufacturing materials, operating principles and physical operational specifications as compared to the predicate devices. The similarities and differences between the proposed and predicate devices have been identified and explained in the comparison matrix which has been included in Section 12 of this submission. These differences have no effect on safety and effectiveness.
Performance Testing:	All testing that is required has been performed. The New Stetic Acrylics have been found to fall within the required limits of the testing. The test results can be found in both the Biocompatibility Testing (Section 15) and the Performance Testing (Section 18) of this submission.

SUMMARY OF TEHCNOLOGICAL CHARACTERISTICS

Following chart shows a comparison of the method of using and the properties declared with respect to the homologous Myerson's economy denture base

PRODUCT	Myerson's economy denture base material.	New Stetic ® Acrylics, New Stetic ® Denture Base Resins.	
510(K) NUMBER	K970522	Not yet assigned	
PARAMETERS		**SIMILARITIES**	**DIFFERENCES**
Method of use	Curing is accomplished by mixing the powder and liquid components at a prescribed ratio (21 g powder/10 ml of monomer) yielding a dough-like material which is the packed into a flask. The flask is then placed in a water bath for curing at: 1. 90 minutes at 165°F followed by 30 minutes in boiling water,, or 2. Overnight at 165°F for at least 9 hours.	Curing is accomplished by mixing the powder and liquid components at a prescribed ratio (2 parts powder to 1 part of monomer by weight) yielding a dough-like material which is the packed into a flask. The flask is then placed in a water bath for curing at: 90 minutes at 165°F followed by 30 minutes in boiling water.	The only difference is in determining the powder / liquid ratio. This difference is related to characteristics of polymer particle size, but not affect the performance of the medical device about ensuring safe use, which is supported by the fulfilling of parameters required by standard ANSI / ADA Specification No. 12:2002 / ISO 1567:1999)
Experimental results			
Flexure Strength. (65MPa Minimum)	74 according to ANSI/ADA Specification No. 12:2002/ISO 1567:1999)	70.8 according to ANSI/ADA Specification No. 12:2002/ISO 1567:1999)	Within specification
Flexural Modulus 2000 MPa Minimum	2459 according to ANSI/ADA Specification No. 12:2002/ISO 1567:1999)	5300 according to ANSI/ADA Specification No. 12:2002/ISO 1567:1999)	Within specification

CONCLUSION

According to previous information products Myerson's Economy Denture Base Material (K970522) and New Stetic ® Acrylics, New Stetic ® Denture Base Resins are technically similar in terms of mechanical properties and specifications related to its use, since both meet the requirements of ANSI / ADA Specification No. 12:2002 / ISO 1567:1999 for Denture Base Polymers, which ensures that the product can be used safely.

New Stetic ® Acrylics, New Stetic ® Denture Base Resins are equivalent to Myerson's Economy Denture Base Material

SUMMARY OF NON-CLINICAL TESTING DATA

Physical properties of polymers are measured in New Stetic's Quality Control Laboratory by means of well-gauged high specialized equipment, according to ANSI/ADA Specification No. 12:2002/ISO 1567:1999 Polymers for Denture Bases.

The most relevant physical properties of Heat-polymerized and Self-polymerized polymers are showed in the following chart:

Heat-polymerized acrylics (Opti-cryl, Veracil, Novacryl, Poti-cryl Pour andEZ-cryl)

Parameters	Requirements ANSI/ADA SPECIFICATION N° 12:2002/ISO 1567:2008	Experimental results
Absorption	Not higher than 32 $\mu g/mm^3$	18.10
Solubility in	Not higher than 1.6 $\mu g/mm^3$	0.8
Flexure Strength	65 MPa Minimum	70.8
Flexural Modulus	2000 MPa Minimum	5300
Residual Monomer Content	2.2% Maximum (In weight)	0.98

Self-polymerized acrylics (Duracryl, O-cryl and Fidelity)

Parameters	Requirements	Experimental results
Absorption	Not higher than 32 $\mu g/mm^3$	19.50
Solubility in	Not higher than 8.0 $\mu g/mm^3$	5
Flexure Strength	60 MPa Minimum	65.4
Flexural Modulus	1500 MPa Minimum	3700
Residual Monomer Content	4.5% Maximum (In weight)	1.45

Other physical properties like color, polishing capacity, translucency, and porosity are evaluated qualitatively. These properties are inside accepted limits.

QUALITY ASSURANCE OF THIS PRODUCT

Acrylic resins are made from the highest quality raw materials through a completely standardized production process which conforms to ISO Standard 9001:2008 and ISO 13485:2003.

Moreover, in its Quality Control Laboratory, New Stetic verifies the fulfilling of ANSI/ADA Specification No. 12:2002/ISO 1567:1999 concerning the quality requisites for the finished product, using specialized equipment.

The most representative machines used for quality control are the following

- Water absorption and solubility: The amount of water that can be absorbed by acrylic resins or the amount of weight that they lose when submerged in water is accurately tested. Acrylic is not soluble in saliva or in any other oral fluid.

- Porosity:The surface of processed acrylics is free from imperfections and porosity.

- Flexural Strength and Flexural Modulus : The degree of distortion suffered by acrylic resins under the occlusion forces that are applied during the use is verified in an INSTRON Testing Machine. The force supported by a resin until its fracture is also measured. This aspect ensures the good clinical performance of resins.

- Translucency: An object placed at the opposite side of the test tube containing acrylic resin must be visible.

- Residual Monomer Content: The amount of monomer that remains after the making of a prosthesis must be minimum in order to avoid possible irritations of oral tissues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

New Stetic
C/O Mr. Auther J. Ward
Regulatory Correspondent
Regulatory and Marketing Services, Incorporated
962 Allegro Lane
Apollo Breach, Florida 33572

MAY 13 2011

Re: K102874
Trade/Device Name: New Stetic Acrylics
Regulation Number: 21 CFR 272.3760
Regulation Name: Denture Relining Repairing or Rebasing Resin
Regulatory Class: II
Product Code: EBI, EBG
Dated: March 14, 2011
Received: March 21, 2011

Dear Mr. Ward:

This letter corrects our substantially equivalent letter of March 28, 2011.

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 (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.

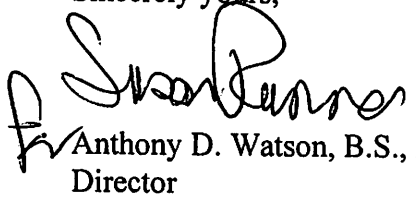
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102874

Device Name: New Stetic Acryics

Indications for Use: The indication for use of the New Stetic® Acrtylics is for the repair or fabrication of the denture base.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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