K130257

APR 0 5 2013

Reliance Orthodontic Products, Inc.
Toll Free 1-800-323-4348 · Phone 630-773-4009 · Fax 630-250-7704
1540 West Thorndale Ave. · Itasca, IL · 60143 · U.S.A.

Section 5.0 **510 (k) Summary**

Note: This summary is provided in accordance with 21CFR807.92 (c).

510 (k) Owners Name:	Reliance Orthodontic Products, Inc. Paul Gange, President
Address:	1540 West Thorndale Avenue Itasca, Il 60143 USA
Phone Number:	630-773-4009
Fax Number:	630-250-7704
Contact Person:	Paula Wendland, Regulatory Affairs Manager (Preparer)

Date 510 (k) Summary was Prepared: August 13, 2012

Medical Device Name:

- Trade name – Pontic Paint
- Common name – Pontic Paint for Thermoplastic Aligners
- Classification name – Accessory to an orthodontic plastic bracket (21CFR872.5470, Product Code NXC, Class II Device)

LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCE IS CLAIMED (PREDICATE DEVICE) [807.92(a) (3)]:

- Flowtain™ with Reliance Orthodontic Products, Inc. and Plastic Conditioner : 510(K083051 and K880792, respectively).

Reliance Orthodontic Products, Inc.
Toll Free 1-800-323-4348 · Phone 630-773-4009 · Fax 630-250-7704
1540 West Thorndale Ave. · Itasca, IL · 60143 · U.S.A.

5.1 DESCRIPTION OF THE APPLICANTS DEVICE:

The Pontic Paint is a light cure coloring agent for thermoplastic aligners. The Pontic Paint is formulated in a viscosity that is easily mixed and bonds chemically to a typically difficult to adhere to surface, a thermoplastic aligner now common in the dental industry. This paint, upon polymerization, is in Vita Shades A1, A2, and B1 allowing the appearance of a realistic tooth under the thermoplastic aligner thereby making a missing tooth situation appear aesthetically pleasing to the patient undergoing orthodontic treatment using clear aligner systems.
The light cure property of the paint allows the user to determine the polymerization time required by simply exposing the adhesive to an LED light source until set.

The Pontic Paint will be marketed in a jar for ease of mixing and application with a brush.

5.2 INTENDED USE AND POPULATION:

The Pontic Paint is intended for use as a light cure coloring agent of thermoplastic aligners.

5.3 PREDICATE DEVICE:

Reliance Orthodontic Products, Inc. Flowtain and Plastic Conditioner, 510(k) submission (K083051 and 880792, respectively) dated 2/20/2009 and 1/15/1988. Flowtain and Plastic Conditioner are similar in intended use for bonding to thermoplastic aligners. Flowtain is similar in compositional basis to the Pontic Paint.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 5, 2013

Ms. Paula Wendland
Regulatory Affairs Manager
Reliance Orthodontic Products, Incorporated
1540 West Thorndale Avenue
ITASCA IL 60143

Re: K130237
Trade/Device Name: Pontic Paint
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NXC
Dated: January 29, 2013
Received: February 7, 2013

Dear Ms. Wendland:

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 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. 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,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Reliance Orthodontic Products, Inc.
Toll Free 1-800-323-4348 · Phone 630-773-4009 · Fax 630-250-7704
1540 West Thorndale Ave. · Itasca, IL · 60143 · U.S.A.

SECTION 6.0 INDICATIONS FOR USE STATEMENT

Indications for Use

510 (k) Number (if known): K130237

Device Name: _____ PONTIC PAINT _____

Indications for Use:

The Pontic Paint is intended for use as a light cure coloring agent of thermoplastic aligners.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Susan Runner, DDS, MA
Mary S. Runner -S
2013.04.04 10:24:09 -04'00'

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

510(k) Number: K130237