K112305

THUNDER TIGER CORP.
NO.7, 6th ROAD INDUSTRY PARK,
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APR 17 2012

510(K) SUMMARY

Vigor Series Low speed dental handpieces & Accessories

1. Date Summary Prepared: August 10,2011
2. Submitter Information

   510(k) Owner: THUNDER TIGER CORP.
   No.7, 6th Road, Industry Park, Taichung, 40755
   Taiwan, ROC

   Contact Person: Jo S.C. Lee/QA Engineer
   jo@thundertiger.com
3. Device Name

   Trade Name: Vigor Series Low speed dental handpieces & Accessories

   Common Name: Dental Handpiece

   Classification Name:

   Handpiece, air-powered, dental (21 CFR 872.4200, Product Code EFB)

   Handpiece, contra- and right-angle attachment, dental (21 CFR 872.4200, Product Code EGS)
4. Predicate Device: E-TYPE CONTRA ANGLE NAC-E, (K962540)

   Surgical Contra-Angel Hanpieces Type WS-56E, WE-75E/KM, WS-92 (K011061)

   ELEC-MATE, MODELS EX-6 SET, EX-6L SET, EX-30 SET (K990954)

   E-TYPE SPEED INCREASER CONTRA ANGLE, EXTERNAL IRRIGATION, INTERNAL IRRIGATION (K972569)

   W&H AIR MOTOR A25 (K944711)

   ATHENA CONTRA ANGLE (K974670)
5. Device Description:

   The Vigor Series Low speed dental handpieces & Accessories are similar to other low-speed dental handpieces currently on the US dental market in design, function, and intended use. The devices are powered by either low speed air motor or electric micro-motor that are reusable and ergonomically shaped, and are provided without a fiber optic light system.

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The Vigor C Low Speed Contra-Angle handpieces are used in conjunction with low speed motors manufactured in accordance with ISO7785-2 and ISO13294 respectively. The bottom design of these contra angle handpieces allows easy "snap-on" connection and removal from the motor. The contra-angle handpieces contain both chip air and water that help with removing debris from teeth cutting.

The Vigor S Low Speed Straight handpieces are used in conjunction with low speed motors manufactured in accordance with ISO7785-2 and ISO13294 respectively. The bottom design of the Low Speed Straight handpiece allows easy connection and removal from the motor. It can be used with a variety of different burrs that conform to the specifications stated in ISO 1797-1. These nose-cones contain both chip air and water that help with removing debris from teeth cutting.

The Vigor A Low Speed Air Motor is used in conjunction with accessories such as contra-angle and straight handpiece that are manufactured in accordance with ISO 7785-2. The locking mechanism of the motor allows easy connection and removal of any add-ons. The motor contains chip air and water that help with removing debris from teeth cutting.

The devices are reused and can be sterilized by the steam autoclave method.

6. Intended Use:

The Vigor Series Low speed dental handpieces & Accessories are powered by either low speed air motor or electric micro-motor for teeth cutting, cavity and crown preparation, restorations and polishing teeth. The Low Speed Contra Angle Dental Handpiece that is intended for removing carious material, cavity and crown preparations, finishing tooth preparations, reducing hard tooth structures, restorations and polishing teeth. The Straight Handpiece contains chip air and water that help with removing debris from teeth cutting.

7. Performance:

Vigor Series Low speed dental handpieces & Accessories have been tested to meet the requirement of ISO 7785-2 standard, ISO 13294 standard, ISO 9687 standard, ISO 9168 standard and FDA guidance "Guidance for Industry and FDA Staff: Dental Handpieces - Premarket Notification [510(k)] Submissions".

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8. Substantial Equivalency:

After analyzing the clinical testing data, it is the conclusion of substances of Vigor Series Low speed dental handpieces & Accessories are substantial equivalent to the predicate device in terms of its intended use, operating principles and functions.

9. Discussion of Clinical Tests Performed:

N/A

10. Conclusion:

The above descriptions coincide with the substantial equivalence made by E-TYPE CONTRA ANGLE NAC-E, (K962540), Surgical Contra-Angel Hanpieces Type WS-56E, WE-75E/KM, WS-92 (K011061), ELEC-MATE, MODELS EX-6 SET, EX-6L SET, EX-30 SET (K990954), E-TYPE SPEED INCREASER CONTRA ANGLE, EXTERNAL IRRIGATION, INTERNAL IRRIGATION (K972569), W&H AIR MOTOR A25 (K944711) and ATHENA CONTRA ANGLE (K974670)

They are substantial equivalent to the predicate device in terms of its intended use, operating principles and functions. Therefore, it can be seen that Vigor Series Low speed dental handpieces & Accessories are both safe and effective for their intended use.

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

Ms. Jo Lee
Quality Assurance Engineer
Thunder Tiger Corporation
No. 7, 6th Road, Industry Park
Taichung, China (Taiwan) 40755

APR 17 2012

Re: K112305
Trade/Device Name: Vigor Series Low Speed Dental Handpieces & Accessories
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EGS
Dated: March 5, 2012
Received: March 6, 2012

Dear Ms. Lee:

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 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,

for

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

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Indications for Use

510(K) Number (If Known): K112305

Device Name: Vigor Series Low speed dental handpieces & Accessories

Indications for Use:

The Vigor Series Low speed dental handpieces & Accessories are powered by either low speed air motor or electric micro-motor for teeth cutting, cavity and crown preparation, restorations and polishing teeth. The Vigor A Low Speed Air Motor is used in conjunction with accessories such as contra-angle, such as The Vigor C Low Speed Contra-Angle handpieces, and straight handpiece, such as The Vigor S Low Speed Straight handpieces. The motor contains chip air and water that help with removing debris from teeth cutting. The Low Speed Contra Angle Dental Handpiece that is intended for removing carious material, cavity and crown preparations, finishing tooth preparations, reducing hard tooth structures, restorations and polishing teeth. The Straight Handpiece contains chip air and water that help with removing debris from teeth cutting.

CAUTION: Federal (US)) law restricts the use of this device to licensed professionals

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF 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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