K112333

JAN 3 0 2012

510(k) Summary

1.	**Name/Address of Submitter:**	**Innovation TAP inc.** 1441, rue du Collège Suite 4 Montréal, Québec H4L 2L8 CANADA
2.	**Contact Person:**	**Emmanuel Montini**, Ph.D., Adm.A Co-President, BCF Certification inc. Phone: (514) 927-4635 Fax: (514) 397-8515 Email: emontini@bcf.ca
3.	**Date Summary Prepared:**	July 15th, 2011
4.	**Classification:**	21 CFR 872.3630
5.	**Common Name**:	Accessory to endosseous dental implant abutment
5.	**Device Name:**	LRT Attachment System
6.	**Product Code:**	NHA

5. **Predicate Devices:**

LRT Attachment System	Locator implant anchor K994257 Ball Attachment system K955372 O-ring Prosthetic Attachment K001638

6. **Device Description:**

Alike the Locator implant, the O-ring Prosthetic Attachment and the Nobel Ball Attachment systems, the LRT Attachment System provides a mean for attaching a removable prosthetic device to an endosseous implant body with the use of a mechanical based retention, hence eliminating permanent structures that prevent easy access to implant abutments.

The LRT Attachment System requires the use of two ball abutments to receive the attachment. The presence of additional implant abutments, although not mandatory, contributes to the support and stability of the prosthesis. These abutments are cone shaped and mate with a reciprocal cover in the denture base.

All predicate devices are snap-on devices. The retentive female part is embedded in the denture part and snaps on another part (e.g. a ball abutment). The retentive

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action relies on the expansion and constriction of the metal female counterpart. The LRT Attachment System provides for an innovative solution by featuring a lock-release retention system activated by digital pressure. This mechanical lock/release action offers ease of manipulation. One of the key elements of the LRT Attachemt System is the easily identified "buttons" of the lock/release mechanism which allow an assistant to manipulate the denture for the severely impaired person.

7. **Indication for Use:**
The LRT Attachment System is indicated for providing a mean of attaching a removable prosthetic device to an endosseous implant body.

8. **Brief Description of Clinical and Non-clinical Testing:** The activation of the mechanism to provide the lock/release function was tested *in vivo* to insure the ease of handling. Over 18 years of clinical testing were performed to fine tune the device and its integration to dental prostheses. In these clinical tests, the LRT Attachment System was found substantially equivalent to the cited predicates. Furthermore, Cytotoxicity in-vitro screening assays in accordance with USP 87 were successfully performed to assess the biocompatibility of the material.

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

Mr. Louis-Paul Marin
Consultant
BCF Certification Incorporation
1100 Rene-Levesque Boulevard, West 25th Floor
Montreal
CANADA H4L 2L8

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Re: K112333
Trade/Device Name: LRT Attachment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: January 19, 2012
Received: January 23, 2012

Dear Mr. Marin:

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 Watson

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

K112333

Indication for Use

510(k) Number (if known):_____

Device Name: **LRT ATTACHMENT SYSTEM**

Indication for Use: The LRT Attachment System is indicated for providing a mean of attaching a removable prosthetic device to an endosseous implant body.

Concurrence of CDRH Office of Device Evaluation

Prescription Use ✓ **OR** **Over-the-counter Use** ____
(per 21CFR 801.109)

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

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