510(k) SUMMARY

SEP 17 2012

1. SUBMITTER INFORMATION

Name:	Tigran Technologies AB
Address:	Medeon Science Park
	SE-205 12 Malmö
	Sweden
Telephone:	+46 40 6939270
Facsimile:	+46 40 650 1666
Contact Person:	Ulf Lundgren, Quality Assurance and Regulatory Manager
Date:	12th of September 2012

2. DEVICE IDENTIFICATION

Trade Name:	Tigran™ PeriBrush™
Common Name:	PeriBrush™
Classification Name:	Scaler, Rotary

3. DEVICE CLASSIFICATION

Device Code:	Rotary Scaler, ELB
Predicate Device	Straumann® TiBrush, K111724

4. DEVICE DESCRIPTION

The Tigran™ PeriBrush™ is made of pure titanium (brush part) and nitinol (stem part). It is intended to use for mechanical debridement of surgically exposed dental titanium implant surfaces to remove plaque and calculus due to peri-implantitis. The product has a connector that fits into the head (chuck) of a dental handpiece accepting instruments complying with ISO 1797-1.

The instrument is delivered sterile. The Tigran™ PeriBrush™ is for single use only.

5. INTENDED USE

Tigran™ PeriBrush™ is intended for:

Tigran™ PeriBrush™ is a debridement instrument for titanium dental implants subjected to peri-implantitis. It is indicated for the open debridement of titanium Implant surfaces in bone defects caused by peri-implantitis.

6. SUBSTANTIAL EQUIVALENCE

In summary, Tigran™ PeriBrush™, is substantially equivalent to the cited predicate device, Straumann® TiBrush, K111724.
They have the same intended use designed for mechanical debridement of dental titanium implant surfaces to remove plaque and calculus due to peri-implantitis.

- Straumann® TiBrush, K111724

7. TECHNOLOGICAL CHARACTERISTICS

Tigran™ PeriBrush™, is substantially equivalent to the cited predicate device.
Following bone loss caused by peri-implantitis, parts of the implant surface becomes exposed to the oral microflora. Before steps towards regenerating the lost bone and reosseointegration of the implant can be taken, the exposed implant surface must be clean from any contamination that could hamper the treatment outcome. This means that the granulation tissue, calculus and/or other macrostructures like excess cementum must be removed.

The device removes contaminants from the surface of the implants. The rotating Tigran™ PeriBrush™ with stiff titanium bristles and flexible stem.

8. PERFORMANCE TESTING

Mechanical tests and simulated clinical performance tests allows for mechanical surface debridement. It is reasonable to state and conclude that the preclinical tests support that Tigran™ Peribrush™, when used as intended under normal conditions, is substantially equivalent.
Biocompatibility testing was conducted in accordance with ISO 10993-5, and all materials tested met the relevant standards.

Sterilization validation was conducted in accordance with ISO 11137.

Clinical evaluation showed that the brush is substantially equivalent.

9. CONCLUSION

The results from the testing conducted demonstrated that the Tigran™ PeriBrush™ functions as intended and is substantially equivalent.

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

SEP 17 2012

Tigran Technologies AB
Mr. Ulf Lundgren
Quality Assurance and Regulatory Manager
Medeon Science Park
SE-205 12 Malmö, Sweden

Re: K121114
Trade/Device Name: Tigran™ PeriBrush™
Regulation Number: 21 CFR 872.4840
Regulation Name: Rotary Scaler
Regulatory Class: II
Product Code: ELB
Dated: August 21, 2012
Received: August 24, 2012

Dear Mr. Lundgren:

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. e 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

INDICATIONS FOR USE

510(k) Number: K121114

Device Name: Tigran™ PeriBrush™

Indications for Use:

Tigran™ PeriBrush™ is a debridement instrument for titanium dental implants subjected to peri-implantitis. It is indicated for the open debridement of titanium Implant surfaces in bone defects caused by peri-implantitis.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices
510(k) Number: K121114

Prescription Use__X____ And/Or Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)