K050341

MAR 2 9 2005

Tactile Technologies

10 Plaut Str., Rabin Scientific Park
Rehovot 76122, ISRAEL Tel: 08-9484740

**510(k) Summary**:

Implant Location Software (ILS)

**Company Name:**

Tactile Technologies Ltd.

**Contact Person:** Zvika Slovin, Ph.D.
CEO

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**Date prepared:** February 7, 2005

**Trade Name:** Implant Location Software.

**Classification name:** Picture archiving and communications system

**Class**: II

**Panel identification:** Radiology devices

**Product code:** LLZ

Tactile Technologies

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**Regulation number: 892.2050**

**Predicate Device:** SimPlant System, Materialise N.V, Belgium cleared under 510(k) no. K033849

**Device description:**

The Implant Location Software is a computer program (software) intended for use as an aid to the dental practitioners in the location of dental implants. The Implant Location System (ILS) guides dental practitioners through the process of planning their patients' dental implant surgery. The system provides information but does not make any clinical decisions for the user.

The software is supplied on disk-on-key.

The Implant location Software is designed to use images acquired from Computer Tomography (CT) scanners, present a graphical image of the planned implants as "virtual implants" on the CT images using DICOM interface standards, provide a summary report that gives planning information for the procedure, and allow user to consult on-line views of the plan during operation.

**Indications for Use:**

The Implant Location Software (ILS) is indicated for use by medically trained people as a software interface and image segmentation system for the transfer of imaging information from a CT scanner and as planning software for dental implant placement.

**Substantial Equivalence:**

The Implant Location Software has the same intended use and the same principle of operation as the SimPlant System, Materialise N.V Belgium, cleared under 510(k) no. K033849 and is therefore substantially equivalent to that device.

**Conclusion:**

The evaluation of the Implant Location Software does not raise any additional concerns regarding safety and effectivity and may therefore be considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2005

Zvika Slovin, Ph.D.
CEO
Tactile Technologies
10 Plaut Str., Rabin Scientific Park
Rehovot 76122
ISRAEL

Re: K050341
Trade/Device Name: Implant Location Software (ILS)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 7, 2005
Received: February 11, 2005

Dear Dr. Slovin:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K050341

Device Name: Implant Location Software (ILS)

Indications for Use:

The Implant Location Software (ILS) is indicated for use by medically trained people as a software interface and image segmentation system for the transfer of imaging information from a CT scanner and as planning software for dental implant placement.

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050341