MAY 2 0 2003

K030820

F. 510(k) Summary

Applicant:	Stick Tech Ltd, PO Box 114, 20521 Turku, Finland Tel: +358-2-4808 2558 Fax: +358-2-241 0032
Contact Person:	Ilkka Kangasniemi, Ph.D.
U.S. Agent to respond to FDA requests:	William M. Troetel, Ph.D. 80 Parkway West Mount Vernon, NY 10552 Tel: (914) 664-1640 Fax: (914) 667-3993 wtroetel@westnet.com

Date Prepared:	March 17th, 2003
Device Trade Name:	everStick™ POST
Device Common Name:	Glass fiber root canal reinforcement
Device Classification Name:	Denture relining, repairing, or rebasing resin (21 CFR §872.3760)

Description of Device:

everStick™ POST is a semi-manufactured product made of glass fibers and polymer/resin matrix. The glass fiber in everStick™ POST is unidirectional which increases the strength and stiffness of the final product perpendicular to the direction of the fibers.

Intended use: Glass fiber reinforcement for dentistry

everStick™ POST is substantially equivalent to everStick™, approved under 510(k) number K011788 dated November 7, 2001 and Ribbond, approved under K913040 dated October7, 1991.

The composition of everStick™ POST is equal with its predicate device, everStick™ with the same technological characteristics. Only the ratio of glass fibers and

polymer matrices are slightly different. The second predicate device Ribbond has the same intended use as everStick™ POST but different technological characteristics that do not raise new questions of safety and effectiveness.

By comparing the ingredients of everStick™ POST to the existing data available from dental polymerizable material it can be stated that everStick™ POST does not expose the dentist or the patient to unacceptable risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 0 2003

Stick Tech Limited
C/O William M. Troetel, Ph.D.
Regulatory Affairs Consultant
80 Parkway West
Mount Vernon, New York 10552

Re: K030820
Trade/Device Name: everStick™ POST
Regulation Number: 21 CFR 872.3810
Regulation Name: Root Canal Post
Regulatory Class: I
Product Code: ELR
Dated: March 14, 2003
Received: March 14, 2003

Dear Dr. Troetel:

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 (PMA), 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 (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. Indications for Use Statement

510(k) Number (if known): K030820

Device Name: everStick™ POST

Indications for Use:

- Intended for use as a fiber reinforced root canal post

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use __
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Ken Mudy for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030820