DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 1999

Abrahim Lavi, Ph.D., M.B.A.
President/CEO
Vilex, Inc.
1801 Route 51 Building 10
Large, Pennsylvania 15025-0724

Re: K991151 and K991197
Trade Name: Cannulated Screws
Regulatory Class: II
Product Code: HWC
Dated: April 1 and 6, 1999
Received: April 6 and 8, 1999

Dear Dr. Lavi:

This letter is being issued in response to your conversation with Mr. Aric Kaiser on April 28, 1999, in which you stated that the Intended Use forms enclosed with our letter dated April 26, 1999, incorrectly described the materials used to manufacture some of the screws described by the submissions referenced above. The corrected Intended Use forms are enclosed and this letter is intended to supercede and replace our letter dated April 26, 1999.

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosures) to 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). You may, therefore, market the devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) NUMBER (IF KNOWN): K991151

DEVICE NAME: Vilex Cannulated Bone Screw/DuVal Cannulated Bone Screw

INDICATIONS FOR USE:

The Vilex/DuVal Cannulated Bone Screw, as designed, has the following Indications for Use: Bone Fractures, Osteotomies, Arthrodeses, Osteochrondritis and Tendon Reattachment. It is intended for, but not limited to, Hand Surgery, Orthopedic Surgery, Plastic Surgery and Podiatric Surgery. The materials used to manufacture this screw are 316L, implant-quality stainless steel and Ti6Al4V, implant-quality titanium. When properly used with Vilex instrumentation, this screw achieves safe purchase and compression for cortical and cancellous bone fixation in the human body.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter-Use
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991151