K022204

510(k) Summary of Safety and Effectiveness

[in accordance with SMDA of 1990, 21 CFR 807.92(c)]

OCT 1 8 2002

Contact: PLUS ORTHOPEDICS
6055 Lusk Blvd.
San Diego, CA 92121

Trade name: VKS Knee System

Common name: Knee Joint Prosthesis

Classification name: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer.
§ 21 CFR 888.3560, Class II, 87 JWH

Equivalence: TC-PLUS™ Solution Knee System (K000666, SE date 10/13/2000)

Characteristics: The VKS Knee System is a tri-compartmental total knee prosthesis comprised of femoral, patellar and tibial components with an intrinsic tibial PE-insert. Standard, and Ultra-Congruent tibial components are available.

Indications: The VKS Knee System is intended as a cemented surface replacement in treating patients who are candidates for primary total knee arthroplasty or revision arthroplasty where bone loss is minimal and the collateral ligaments are intact. It is not indicated when significant bone loss and/or ligamentous deficiencies have occurred due to tumors, trauma, infection, revision, or connective tissue disorders.

Contraindications: Contraindications include acute or chronic infections (local or systemic) or a history of infection; severe muscular, neurological, or vascular deficiencies which compromise the affected extremity; bone defects or insufficient bone quality which may affect the stability of the implant; any concomitant illness which may compromise the function of the implant; severe obesity; allergy to the implant materials; subluxation of the femur against the eminentia; ligament instability; severe varus or valgus misalignment; retropatellar degenerative arthritis; extension contractures over 10°.

Performance data: Biomechanical Testing has been provided. All test results are sufficient for *in vivo* loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 8 2002

Ms. Rebecca Wahl
Consultant, Regulatory Affairs
PLUS Orthopedics
6055 Lusk Boulevard
San Diego, California 92121

Re: K022204
Trade/Device Name: VKS Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Codes: JWH
Dated: October 3, 2002
Received: October 4, 2002

Dear Ms. Wahl:

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 and additionally 21 CFR Part 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 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). 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,

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

Enclosure

510(k) Number: K022204

Device Name(s):

VKS KNEE SYSTEM

Indications for Use:

The VKS Knee System is intended as a cemented surface replacement in treating patients who are candidates for primary total knee arthroplasty or revision arthroplasty where bone loss is minimal and the collateral ligaments are intact. It is not indicated when significant bone loss and/or ligamentous deficiencies have occurred due to tumors, trauma, infection, revision, or connective tissue disorders.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022204

Prescription Use X OR Over-The-Counter-Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)