

K930657

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Summary of Safety and Effectiveness Information The D-C-S System

The D-C-S System is intended for use in the treatment of fracture, deformity, spondylolisthesis, spinal stenosis, tumors and metastases, spondylitis, and multi-operated spine. It is intended for use in stabilization of the cervical spine (C1-C7) using a posterior surgical approach. The implant is intended to be removed from the cervical spine once stabilization or correction is achieved.

The D-C-S System is made of ASTM F136 implant grade titanium. The System consists of a central threaded screw, available in various lengths, with both left and right threads, two configurations of clamps with integral swivels, and a milled hexagonal nut. Both C and N clamps are available, with the C clamps intended for use in C1/2 and C1/3 and the N clamps for use at C2 through C7.

The D-C-S System is provided fully assembled for use. The system consists of a clamp is threaded onto each end of the screw, which can be adjusted by the surgeon by turning the milled hexagonal nut to achieve compression. The clamps are slipjoint tiltable and securely engage the vertebral laminae. The screws are available in lengths of 30, 35, 40, and 45 mm and with right and left threads in each size. The hooked clamps with integral swivels are available with center holes to fit each screw size. Two tools are supplied to install the system, a forceps for holding and a wrench for turning the hex nut.

The D-C-S System is substantially equivalent to the Halifax Spinal Clamp System. Each of these devices is for the same or similar intended uses in fixation, stabilization, and compression of the posterior cervical spine. The D-C-S and Halifax Systems consist of the same types of components and operate according to the same principles. Thus, the safety and effectiveness of the D-C-S System is the same as for the predicate device.



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Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

Ms. Patricia B. Shrader
.Hogan & Hartson
for PINA Vertriebs
555 13th Street NW
Washington, D.C. 20004-1109

Re: K930657
D-C-S System
Product Code: KWP
Regulatory Class: II
Dated: June 1, 1994
Received: June 2, 1994

Dear Ms. Shrader:

We have reviewed your Section 510(k) notification of intent to market the device system referenced above and we have determined the device system is substantially equivalent to device systems marketed in interstate commerce prior to May 28, 1976. This decision is based on your device system being found equivalent only to similar device systems labeled and intended to be fixed/attached to the cervical spine by hooks. You may, therefore, market your device system subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act).

The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration. Note that labeling or otherwise promoting this device system for pedicular screw fixation/attachment would cause the device system to be adulterated under 501(f)(1) of the Act.

This device system, if intended for use in pedicular screw fixation/attachment, would be found not substantially equivalent and would be a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. You may not label or in any way promote this device system for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. Therefore, in order to prevent off-label promotion, the

labeling must include the following statement, "**WARNING:** This device system is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.";

2. All labeling for this device system, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system is intended for cervical hook fixation/attachment only; and
3. Any pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column of this device system is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device system for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conduct of the investigation.

If your device system 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 system can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device system in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

FDA advises that the use of the D-C-S System with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical testing of a spinal system consisting of the subject device components and other device components, whether yours or other manufacturers', may also be required.

This letter immediately will allow you to begin marketing your device system intended for cervical hook fixation/attachment only. An FDA finding of substantial equivalence of your device system to a legally marketed predicate device system results in a classification for your device system and permits your device system to proceed to the market, but it does not mean that FDA approves your device system. Therefore, you may not promote or in any way represent your device system or its

labeling as being approved by FDA. If you desire specific advice on the labeling for your device system please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Maie A. Schroeder, MS PT
for Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health