

EXHIBIT G

JUL 16 1997

510(k) SUMMARY

THE CONTOUR SPINAL FIXATION SYSTEM

ARCAN ORTHOPEDICS

3903 Harrison Blvd., Ogden, Utah 84403 Phone 801-399-5516 - Fax 801-399-9517

1. Description

The Contour Spinal Fixation System consists of rods, hooks, screws, clamps, and plates designed for attachment to the noncervical spine to restore or maintain the normal alignment and assist in obtaining arthrodesis of abnormal vertebral motion segments. The implants are made of 22-13-5 stainless steel conforming to ASTM-138. Three types of rods pre-cut to a variety of lengths are provided. The first rod is a simple straight rod. The second has a right angle bend with a short arm on one end. The third has an expansion with a screw hole on one end. The system uses three types of clamps. One clamp consists of an eye-bolt-“C” shaped clamp combination which connects longitudinal rods with a crosslink rod. A second clamp is shaped like a “C” which encircles and is compressed to the rod by the proximal threads of a bone screw engaging and lagging the threaded side of holes placed through the ends of the “C”. The third clamp is similar to the second clamp except the compressing screw is a simple screw which is also used to attach a crosslink plate. Extending from and incorporated as part of the third clamp is a short rod, which, when connected to a “C” clamp-bone screw combination, allows insertion of a bone screw in any horizontal or sagittal angle or translational distance from a longitudinal rod. The system has two types of screws provided in a variety of lengths. One screw locks to the rod by engaging the threads of a rod with a threaded hole expansion at one end or by the proximal threads of the screw lagging and compressing a “C” clamp around a rod. The second screw is secured by an eye-bolt in the head of the screw. Two mechanisms are used for hook-rod connection. One locks to the rod with an eye-bolt. The second has a lateral facing “U” shaped opening for the rod entrance. The rod is pushed into and locked at the closed end of the “U” by a tapered locking screw.

2. Identification of Predicated Device

The Contour Spinal Fixation System is substantially equivalent to the Harrington rod, hook, sacral screw, lag screw inserted into the pedicle of L5, and the Dwyer anterior vertebral screw system all manufactured and distributed commercially by Zimmer of Warsaw, Indiana prior to May 28, 1976.

### 3. Intended Use

When used as a hook, rod, and ileo-sacral screw fixation system(KWP) T1-S1, the indications for use are:

- spondylolisthesis
- fracture
- spinal stenosis
- deformities(scoliosis, kyphosis, lordosis)
- pseudarthrosis
- tumor
- multi-operated back or revision of previous surgery

The system is indicated for pedicle screw fixation(MNH) L3-S1, ilium as follows:

When used as a pedicle screw fixation system the device system is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

### 4. Safety and Effectiveness

Beginning in 1950 with the posterior insertion of hooks, rods and later screws by Dr. Paul Harrington, and anterior vertebral body screw fixation by Dr. A.F. Dwyer in 1969, numerous studies have documented the advantage of instrumentation to correct deformity and enhance fusion rates for a variety of spinal abnormalities. Modifications of the Harrington and Dwyer devices have resulted in improved correction of deformity, more rigid fixation, and the ability, in many cases, to eliminate the need of external support or bracing. Such systems include the Cotrel-Dubousset, TSRH, Rogozinski, ISOLA, Modulock, MOSS, and the Bryan Posterior Spinal Fixator(BPSF). The systems differ in how the screws and hooks attach to the rods, but the basic construction and indications for their use in patients are similar. Although Harrington used pedicle screws in the lumbar spine and these were commercially distributed by Zimmer of Warsaw, Indiana, prior to 1976, the use of pedicle screws for lumbosacral fusions became more common in 1985 and a vast experience of their use since then has been recorded. Mardjeko et. al completed a meta-analysis review of 25 papers published between 1970-93 involving the treatment of degenerative spondylolisthesis by no surgery, posterior decompression alone, decompression and bone grafting without instrumentation, decompression bone grafting and FDA Class II device instrumentation, decompression, grafting and pedicle screw instrumentation, and anterior fusion. Mardjeko concluded that 1) spinal fusion significantly enhanced patient satisfaction,

2) instrumentation enhanced the fusion rate, and 3) FDA Class II devices and pedicle screw instrumentation are equivocal in fusion rate, patient satisfaction, and complications. An open, nonblinded, Historical Cohort study by Dr. Hansen Yuan including 2,684 patients with degenerative spondylolisthesis revealed a higher fusion rate and better clinical results in patients treated with pedicle screw fixation compared to the non-instrumented and conventional non-pedicle screw instrumented patients. Dr. T.A. Zdeblick randomly divided 124 patients undergoing fusion of the lumbosacral spine for degenerative and isthmic spondylolisthesis into three groups. Group I had simple autogenous bone grafting, Group II had grafting plus Luque II screw plate fixation, and Group III had grafting plus TSRH pedicle screw rod fixations. The fusion rate for Groups I, II, and III were 65%, 77%, and 95% respectively. The good to excellent patient satisfaction rate was 71% for Group I, 89% for Group II, and 95% for Group III.

#### References

- Dwyer, A. F.: Clin. Orthop., 62:192, 1969.  
Harrington, P. R.: J. Bone Joint Surg, 44A:591-610, 1962.  
Mardjeko S. M. Spine 19(20S):2256S-2265S, 1994.  
Yuan IIA, et al. Spine 19(20S):2279S-2296S, 1994.  
Zdeblick, T.A.: Spine 18(8):983-991, 1993.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Donald W. Bryan, M.D.  
Arcan Orthopedics  
3903 Harrison Boulevard  
Ogden, Utah 84403

JUL 16 1997

Re: K971457  
Contour Spinal Fixation System (CSFS) - modification  
Regulatory Class: II  
Product Codes: KWP and MNH  
Dated: June 7, 1997  
Received: June 10, 1997

Dear Dr. Bryan:

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 (for the indications for use stated in the enclosure) to device systems marketed in interstate commerce prior to May 28, 1976 or to devices that have been reclassified in accordance with the provisions of the Federal, Food, Drug, and Cosmetic Act (Act). This decision is based on your device system being found equivalent only to similar device systems labeled and intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. You may, therefore, market your device system subject to the general controls provisions of the Act and the limitations identified below.

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. Note that labeling or otherwise promoting this device system for pedicular screw

fixation/attachment for indications other than severe spondylolisthesis, as described above, would cause the device system to be adulterated under 501(f)(1) of the Act.

This device system, when intended for pedicular screw fixation/attachment to the spine for indications other than severe spondylolisthesis, as described above, is 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. All labeling for this device, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system using pedicle screws is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.
2. You may not label or in anyway promote this device system for pedicular, screw fixation/attachment to the cervical, thoracic or lumbar vertebral column for intended uses other than severe spondylolisthesis, as described above. The package insert must include the following statements:

**WARNINGS:**

- When used as a pedicle screw system, this device system is intended only for grade 3 or 4 spondylolisthesis at the fifth lumbar - first sacral (L5-S1) vertebral joint.
- The screws of this device system are not intended for insertion into the pedicles to facilitate spinal fusions above the L5-S1 vertebral joint.
- Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.

- Potential risks identified with the use of this device system, which may require additional surgery, include:

device component fracture,  
loss of fixation,  
non-union,  
fracture of the vertebra,  
neurological injury, and  
vascular or visceral injury.

See Warnings, Precautions, and Potential Adverse Events sections of the package insert for a complete list of potential risks.

3. Any pedicular screw fixation/attachment for intended uses other than severe spondylolisthesis, as described by item 1, for this device 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 for pedicular screw fixation/attachment for intended uses other than severe spondylolisthesis, as described above, must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an investigation.
4. Any previous warning statements identified as part of previous 510(k) clearances or required by OC/Labeling and Promotion which stated that a component/system was not approved for screw fixation into the pedicles of the spine must be replaced by the warnings of items 1 and 2 above.

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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General

(GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 device 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.

FDA advises that the use of your device 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 those of other manufacturers, may also be required.

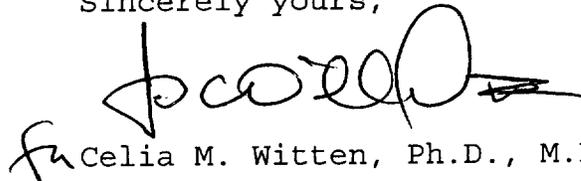
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be

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obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.

Director

Division of General and

Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

EXHIBIT F

510(k) Number (if known): K971457

Device Name: The Contour Spinal Fixation System(CSFS)

Indications For Use:

When used as a hook, rod, and ileo-sacral screw fixation system (KWP) T1-S1, the indications for use are:

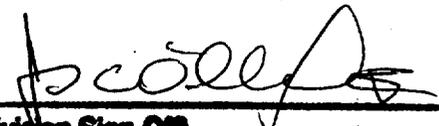
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of General Restorative Devices  
 510(k) Number K971457

Prescription Use  (Per 21 CFR 801.109)

OR

Over-The-Counter Use