

K960444

Exhibit 2
510(k) Summary

510(k) Summary

JAN 24 1997

Rod to Rod Connector

Smith & Nephew Orthopaedics
1450 Brooks Road
Memphis, TN 38116

1. Description

The Rod to Rod Connector is manufactured of ASTM F 138 stainless steel. The device consists of a set screw, a hex nut, a crossbar clamp, an extended clamp, and an eyebolt. The eyebolt is adjustable with the hex nut to provide varying offsets from rod to rod. The Rod to Rod Connector is intended to connect two contralateral 1/4" Rogozinski Spinal System rods.

2. Identification of the Predicate Device

The Rod to Rod Connector is substantially equivalent to the AcroMed Modular Cross Connector Components, Dyna-Lok Spinal System Crosslink Plate, TSRH Spinal System Crosslink, the Isola Spinal System transverse rod connectors, and the Rogozinski Spinal Rod System crossbar.

3. Intended Use

The Finn Rod to Rod Connector is used as part of the Rogozinski Spinal Rod System. The Rod to Rod Connector is designed to attach two 1/4" Rogozinski Spinal Rods to provide temporary stability to the lumbosacral spine during the development of a solid spinal fusion. The Finn Rod to Rod Connectors are designed to be part of a construct that consists of Rogozinski rods attached to the spine with hooks, bolts and/or screws. The Finn Rod to Rod Connectors when used in constructs with spinal screws or bolts placed in the pedicles are 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. Otherwise, the Finn Rod to Rod Connectors when used in constructs with spinal screws or bolts are intended for sacral iliac attachment only in the treatment of degenerative disc disease of the lumbar spine, pseudoarthrosis, spinal stenosis, scoliosis, spondylolisthesis, fracture, failed back syndrome/unsuccessful previous attempts at spinal fusion, or tumor resection. Degenerative disc disease of the lumbar spine is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

The Rogozinski System is limited to noncervical spine use. The levels of pedicle screw / bolt use for this system are limited to L3-S1 or iliac screw fixation.

4. Information Bearing on Safety and Effectiveness

Mardjetko et al.¹ presented the results of a meta-analysis of the literature relating to degenerative spondylolisthesis. Accepted for inclusion in this meta-analysis were 25 papers published between 1970 and 1973 representing 889 patients presenting with degenerative spondylolisthesis with radicular leg pain or neurogenic claudication involving the lumbar spine from L1-S1. Degenerative spondylolisthesis is characterized by degenerative arthritis of the facet joints in association with disc degeneration. Remodeling of the facet joint allows anterolisthesis of the cephalad on the cauda lumbar vertebra This

meta-analysis stratified papers into the following groups: (i) Nonoperative/natural history - 3 papers with 278 patients total, (ii) Posterior decompression procedures without fusion - 11 papers with 216 patients total, (iii) Posterior decompression with fusion procedure without instrumentation - 6 papers with 84 patients total, (iv) Posterior decompression with fusion with "control" device, i.e., legally marketed Class II devices - 4 papers with 138 patients total, (v) Posterior decompression with fusion with pedicular instrumentation - 5 papers with 101 patients total, (vi) Anterior spinal fusion - 3 papers with 72 patients total. Mardjetko stated that the recognized advantages of pedicular instrumentation over control devices as an adjunct to posterolateral spinal fusion include (i) the ability to achieve three-column spinal control from a posterior approach, (ii) the restoration and maintenance of physiologic spinal alignments in all planes, (iii) no space-occupying metallic devices within the degenerative lumbar spinal canal, and (iv) the ability to achieve fixation across segments with deficient or absent posterior spinal elements, potentially minimizing the spinal segments requiring instrumentation and fusion. Mardjetko concluded that the results of this meta-analysis support the clinical impression that in the surgical management of degenerative lumbar spondylolisthesis, spinal fusion significantly improves patient satisfaction, and adjunctive spinal instrumentation enhances spinal fusion rates. FDA Class II devices and pedicular instrumentation are comparable with regards to rates of fusion, patient satisfaction, and complications. The results of an open, nonblinded, historical cohort study presented by Yuan et al.ⁱⁱ support Mardjetko findings. This historical cohort study collected data on patients who had undergone spinal fusions using pedicle screw devices as well as those who had received legally marketed spinal fusion devices or no instrumentation at all. A total of 2,684 patients with degenerative spondylolisthesis were included in this cohort study with 2,177 (81.1%) in the pedicle screw group, 456 (17.0%) in the noninstrumented group, and 51 (1.9%) in the non-pedicle screw instrumentation group. The safety of pedicle screw devices for the treatment of degenerative spondylolisthesis was assessed by analyzing the nature and frequency of intraoperative and postoperative events. Intraoperative events related to pedicle screw devices occurred infrequently. The rate of implant breakage was extremely low (0.2%). The remaining intraoperative events were felt to be related to surgical technique rather than the implant. Pedicle screw device related postoperative events were comprised mainly of screw fracture and screw loosening. Since the dominant control group for degenerative spondylolisthesis was non-instrumented fixations, no such rate comparisons for these events could be made. However, many of these events were without clinical consequence. For postoperative events that could have occurred in both treatment groups, the nature and frequency of these events were comparable. Additionally, the time adjusted rates of events were not statistically different between the two treatment groups. The rate of reoperation was higher in the pedicle screw group than in the noninstrumented group (17.6% versus 15.0%) primarily due to device removals. The rates of refusion and other reoperations, which can occur in both treatment groups were similar. In terms of effectiveness, the pedicle screw treatment group had a statistically higher rate of fusion than the noninstrumented control group (simple: 89.1% versus 70.4%). Additionally, the time to fusion tended to be faster for the pedicle screw group patients. Maintenance of spinal alignment and degeneration at other levels, although not statistically different, favored the pedicle screw fixation group. Yuan concluded that the benefits of pedicle screw fixation for the treatment of degenerative spondylolisthesis were demonstrated in significantly higher fusion rates compared to conventional non-instrumented control surgical treatments with pedicle screw patients achieving better overall clinical outcomes. Garfinⁱⁱⁱ in a summation of the works of Mardjetko et al. and Yuan et al. states that data derived from a scientifically valid study show that pedicle screws-based devices can offer help to a significant number of people. The literature review as well as the cohort study show that the fusion rate markedly improves when internal fixation is added and that pedicle screw systems are at least as effective as the currently marketed, commercially available Class II instrumentation in terms of increasing the fusion rate. Garfin further states that although the complication rates are higher in those that have instrumented fusions versus in situ fusion, pedicle screw devices have no higher complication rates and no more significant complications than the currently marketed, commercially available Class II instrumentation. Therefore, in properly chosen patients, matched to the appropriate device and procedure, the results in obtaining a fusion and successful outcome may be better using pedicle screw devices, than with other system that are currently available and approved for use in the United States. Zdeblick^{iv} reported the results of a randomized study of 124 patients undergoing lumbar or lumbosacral fusion for degenerative conditions of the spine. Patients were randomly assigned to one of the following three treatment groups: (I)

posterolateral fusion using autogenous bone graft, (II) autogenous posterolateral fusions supplemented with the Luque II screw/plate fixation system (Sofamor/Danek), and (III) autogenous posterolateral fusions supplemented with the TSRH screw/rod fixation system (Sofamor/Danek). Of the 124 patients entered into the study, 56 presented with degenerative or isthmic spondylolisthesis: 21 in Group I, 18 in Group II and 17 in Group III. The fusion rate for degenerative spondylolisthesis for Groups I, II, and III were 65%, 50%, and 86%, respectively.

The fusion rate for isthmic spondylolisthesis for Groups I, II, and III were 80%, 89%, and 100%, respectively. Overall fusion rates for Groups I, II and III were 65%, 77% and 95%, respectively. Zdeblick also assessed each patient clinically and assigned each a rating of either "excellent", "good", "Fair", or "poor". The overall good or excellent clinical results were 71% in Group I, 89% in Group II and 95% in Group III. Zdeblick concluded that pedicle screw fixation led to a significantly higher rate of fusion in degenerative lumbar disease than did fusion without instrumentation and that the clinical results mimic the radiographic results in all three Groups.

- i. Mardjetko SM, Connolly PJ, Shott S: Degenerative Lumbar Spondylolisthesis: A Meta-Analysis of Literature 1970- 1993. *Spine* 19(20S):2256S-2265S, 1994.
- ii. Yuan HA, Garfin SR, Dickman CA, Mardjetko SM: A Historical Cohort Study of Pedicle Screw Fixation in Thoracic, Lumbar, and Sacral Spinal Fusions. *Spine* 19(20S):2279S-2296S, 1994.
- iii. Garfin SR: *Summation*. *Spine* 19(20S):2300S-2305S, 1994.
- iv. Zdeblick TA: A Prospective, Randomized Study of Lumbar Fusion. *Spine* 18(8):983-991, 1993.