

ACPii Anterior Cervical Plate System
510(k) Summary
K970806
MAY - 2 1997 April, 1997

- I. **Company:** Sofamor Danek USA
 1800 Pyramid Place
 Memphis, Tennessee 38132
 (901) 396-3133
- II. **Product Name:** ACPii Anterior Cervical Plate System
- Classification Name:** Spinal intervertebral body fixation orthosis
- III. The ACPii Anterior Cervical Plate System consists of a variety of shapes and sizes of bone plates (set screws and washers are pre-assembled to plates), screws and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. The implant components will be made from titanium alloy as described by ASTM F-136 and may be supplied either sterile or non-sterile.
- IV. The ACPii Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

- V. The ACPii Anterior Cervical Plate System was claimed to be substantially equivalent to commercially available cervical plating systems. Literature concerning these devices was supplied in support of establishing equivalence.

Mechanical test data were provided in support of this notification.