

**IX. 510(k) Summary**

SUBMITTER: DePuy Spine, Inc.  
325 Paramount Drive  
Raynham, MA 02767

CONTACT PERSON: Frank S. Jurczak

DATE PREPARED: September 5, 2007

CLASSIFICATION NAME: Spinal Intervertebral Body Fixation Orthosis

PROPRIETARY NAME: SWIFT™ Plus Anterior Cervical Plate System

PREDICATE DEVICES: SWIFT™ Anterior Cervical Plate System  
(K040655)

EAGLE™ Plus Anterior Cervical Plate System  
(K070994)

DEVICE DESCRIPTION: The SWIFT Plus Anterior Cervical Plate System consists of an assortment of plates and screws.

The SWIFT Plus Anterior Cervical Plate System also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.

INTENDED USE: The indications for use for the modified devices described in this submission are the same as those for the previously cleared SWIFT Anterior Cervical Plate System. The indications are as follows:

The SWIFT™ Plus Anterior Cervical Plate System is intended for anterior cervical intervertebral body fixation. This system is indicated for patients in which stability is desired following anterior cervical fusion for the indications listed below. The intended levels for treatment range from C2 to T1.

Indications include symptomatic cervical spondylosis, trauma, fracture, post-traumatic kyphosis or lordosis, tumor, degenerative disc disease (defined as

## SWIFT™ Plus Anterior Cervical Plate System

---

discogenic pain with degeneration of the disc confirmed by history and radiographic studies), re-operation for failed fusion, or instability following surgery for the above indications.

### MATERIALS:

Manufactured from ASTM F-136 implant grade titanium alloy.

### PERFORMANCE DATA:

Performance data were submitted to characterize the SWIFT Plus Anterior Cervical Plate System.