BAK/Cervical (BAK/C®) Interbody Fusion System - P980048

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	BAK/Cervical (BAK/C®) Interbody Fusion System
Manufacturer:	Sulzer Spine-Tech
Address:	7375 Bush Lake Road, Minneapolis, Minnesota 55439
Approval Date:	April 20, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/p980048a.pdf

What is it? This device is a system of surgical tools and special screws used to help make the cervical spine (the neck) more stable and reduce pressure on the spinal nerves. The screws, which are hollow and have holes in their sides, are implanted into the neck bones, causing them to grow together ("spinal fusion"). This surgical procedure is often used when there is damage to the spinal discs (the "cushions" between the bones of the spine).

How does it work? In the surgical procedure that uses this device, the surgeon goes into the neck from the front. A hole is made between the neckbones to receive the screw. Bits of the patient's own bone from the drilled hole, and possibly some more taken from the hip bone, are put into the hollow screw, which is then screwed into the hole. The screw lifts and separates the bones and, in time, the bits of bone grow into the spine and help hold it together.

When is it used? This device is for fully grown people who have a damaged disc between the third and seventh neck bones (C-3 to C-7 (degenerative disc disease) and have symptoms, such as pain, that show that something is pressing on a nerve (a radicular symptom).

What will it accomplish? This device may help stabilize the affected part of the neck. This can alleviate pain in the neck, shoulder or arm, and reduce muscle weakness and numbness. In a study by the implant manufacturer, 64 out of 100 patients who were treated with this device had a good result, meaning their neck bones joined and they had less neck, shoulder, or arm pain, stronger muscles and less numbness.

When should it not be used? This device should be used only by surgeons who have received special training in its use. It should not be used on patients who have an active infection, or who are allergic to the titanium alloy from which it is made.

Additional information: The SSED and Labeling is available at: http://www.fda.gov/cdrh/pdf/p980048.html **Other:** http://www.nlm.nih.gov/medlineplus/backpain.html

(Updated 6/4/2001)