



New Humanitarian Device Approval

PROSTALAC HIP TEMPORARY PROSTHESIS- H000004

FDA approved this device under the Humanitarian Device Exemption (HDE) program <http://www.fda.gov/cdrh/ode/hdeinfo.html>. See the links below to the Summary of Safety and Probable Benefit (SSPB) and other sites for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: PROSTALAC Hip Temporary Prosthesis
Manufacturer: DePuy Orthopaedics, Inc., a Johnson & Johnson Company
Address: P.O. Box 988, 700 Orthopaedic Drive, Warsaw, IN 46581-0988
Approval Date: March 23, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/H000004a.pdf>

What is it? This device is a **temporary** artificial hip (total hip replacement). Its parts are:

- a metal stem and ball that fits in a hole in the top of the large leg bone (femur),
- a plastic cup that attaches to the hip-bone, and
- bone cement that has two antibiotics (tobramycin sulfate and vancomycin hydrochloride).

You may find a picture of an artificial hip at: <http://text.nlm.nih.gov/nih/cdc/www/98hip.gif>

How does it work? If your artificial hip is infected, this temporary device replaces it for about 3 months. Its antibiotics may help heal your infection so you can get a new artificial hip. Your doctor will give you other antibiotics too to help heal your infection.

When is it used? If you have an infected artificial hip this device may help you. It is used only when you have two-stage surgery. Two-stage surgery is when:

- your doctor takes out your infected artificial hip,
- treats you with antibiotics until your infection is healed, and
- then puts in a new artificial hip

We do not know how useful this device will be for every patient. For a device like this, which was approved under FDA's special Humanitarian Device Exemption Program, the hospital where your doctor plans to treat you will have to agree with your doctor that it is right for you.

What will it accomplish? It may:

- allow you to move around some while you are healing,
- help keep scars from forming in your hip joint between surgeries and
- help treat your infection.

When should it not be used? You should not have this device if you

- have kidney problems, because antibiotics may harm your kidneys,
- plan on placing a lot of weight on your hip, because it may break, or
- are allergic to its antibiotics

Additional information: The Summary of Safety and Probable Benefit will be available at:
<http://www.fda.gov/cdrh/ode/H000004sum.html>

Other: Artificial Hip Replacement: <http://text.nlm.nih.gov/nih/cdc/www/98txt.html>

(Updated 4/09/2001)