U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Zimmer M/L Taper with Kinectiv Technology Prosthesis Femoral Stems and Necks Higher than Expected Levels of Manufacturing Residues

Recall Class: Class I

Date Recall Initiated: June 8, 2015

Device: **Affected lot numbers and item descriptions are listed below**.

Manufacturing and distribution dates: March 31, 2015 through April 20, 2015

Use: The Zimmer M/L Taper with *Kinectiv* Technology Femoral Stems and Necks are Tivanium® alloy implants used for hip replacements that allow the surgeon to fit the implant specifically to the patient. During hip replacement surgery, the damaged portions of the hip joint are removed and replaced with an integrated system of products, which includes the femoral stem and neck.

Recalling Firm:
Zimmer, Inc.
1800 West Center Street
Warsaw, IN 46580

Reason for Recall: The company found a process monitoring failure that led to higher than expected amounts of manufacturing residues left on the devices. These residues can cause serious adverse health issues including allergic reactions, pain, infections, or death. Use of these products may require the need for a revision surgery to replace the affected implant.

The company has not received any complaints related to this issue for any of the lots in distribution.

Public Contact: Questions or concerns should contact the customer call center at 1-877-946-2761 between 8:00 am and 5:00pm EST.

FDA District: Detroit District Office

More Information about this Recall:
On May 18, 2015, Zimmer issued recall notification letters and instructions for distributors and hospital staff.

Instructions for distributors:

1. Review the notification and ensure affected personnel are aware of the contents.