



New Device Approvals

TMJ (Temporomandibular Joint) Metal-on-Metal Total Joint Replacement Prosthesis System

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: TMJ (Temporomandibular Joint) Metal-on-Metal Total Joint Replacement Prosthesis System
Manufacturer: TMJ Implants Inc.
Address: 17301 W. Colfax Ave. Suite 135, Golden, Colorado 80401
Approval Date: January 5, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/p000023a.pdf>

What is it? The metal-on-metal total joint replacement is intended to act as an implant to replace the natural temporomandibular joint (TMJ) (i.e., the moving joint between the temporal and mandibular bones). Diseases involving this joint can cause extreme pain and inability to open the mouth normally. ([Illustration](#))

How does it work? Patients who meet certain criteria are selected to have a surgical procedure under general anesthesia to remove the natural condyle (a rounded bony projection) and the soft tissue disk the condyle rotates against and replace them with this implant. This implant will replace the normal temporomandibular joint and allow a patient to functionally open and close the mouth and chew.

When is it used? This implant is used when the natural temporomandibular joint is severely damaged or diseased.

What will it accomplish? This implant is intended to help reduce pain and restore jaw function.

When should it not be used? This implant should not be used in patients with head and neck infection or malignancy, known allergy to any of the components of the system, or inability to control muscle exertion (such as clenching or grinding the teeth) that may overload and fracture the device.

Additional information: Summary of Safety and Effectiveness is available at:
<http://www.fda.gov/cdrh/pdf/p000023.html>
