FDA's Role in Approving TMJ Implants and Monitoring Their Safety

Among its many responsibilities, the FDA is charged with helping to ensure the safety FDA's Role in Approving TMJ Implants and Monitoring Their Safety and effectiveness of medical products, including medical devices used to treat Temporomandibular Disorder (TMD), such as Temporomandibular Joint (TMJ) implants.

The FDA reviews TMJ implants before they are marketed and continues to monitor their performance and to take action when problems are discovered. The FDA monitors reports of adverse events and other problems with medical devices, and alerts health professionals and the public when needed to ensure proper use of devices and the health and safety of patients.

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FDA-Approved TMJ Implants

The FDA requires premarket approval (PMA) applications for all TMJ implants. A PMA is the most stringent type of device marketing application required by the FDA. The FDA approves a PMA based on a determination that the PMA contains sufficient valid scientific evidence to provide reasonable assurance of the safety and effectiveness of that the device for its intended use. For information about approved TMJ implants, you may search our public database for

- Joint, temporomandibular, implant (Product Code LZD) (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?start_search=1&applicant=&tradename=&productcode=lzd&pmanumber=&supplementnumber=&advisorycommittee=&docketnumber=&supplemen
- Glenoid fossa prosthesis (Product Code MPI) (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?start_search=1&applicant=&tradename=&productcode=MPI&pmanumber=&supplementnumber=&advisorycommittee=&docketnumber=&suppleme

FDA Device Tracking Regulation

The FDA's Device Tracking Regulation (/medical-devices/postmarket-requirements-devices/medical-device-tracking) requires manufacturers, distributors, and hospitals to establish systems to track certain medical devices whose failure may pose a serious health risk to the public. These tracking systems help manufacturers contact patients with information regarding significant device problems, changes to the device label, or if an implant needs to be recalled. Since 1993, the FDA has included TMJ implants on the list of tracked devices because failure of these implanted devices would be reasonably likely to have serious, adverse health consequences. The FDA continues to list TMJ implants as tracked devices because the potential serious, adverse health consequences are still applicable to TMJ implants on the market today.

The manufacturing companies and the FDA also have other approaches to notify the public about a recall (removal or correction) (/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices). Some examples include changing the device label, issuing press releases, posting on social media sites, sending emails, and posting on FDA.gov and company websites. For more details, review the FDA guidance, Public Warning and Notification of Recalls Under 21 CFR Part 7 (/regulatory-information/search-fda-guidance-documents/public-warning-notification-recalls-under-21-cfr-part-7-subpart-c).

Post-Approval Studies of TMJ Implants

As a condition of approval for each approved TMJ implant device, the FDA required that the manufacturer conduct a post-approval study (/medical-devices/postmarket-requirements-devices/post-approval-studies-program), to help assure the continued safety and effectiveness of approved devices. A post-approval study is intended to gather specific information to address questions about the postmarket performance of or experience with an approved medical device. The Post-Approval Studies Database provides general information regarding each study:

- Nexus CMF TMJ Fossa-Eminence/Condylar Prostheses (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=89805&c_id=175)

- Nexus CMF TMJ Fossa-Eminence Prosthesis (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=90175&c_id=180)
- TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis: Long Term (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=90012&c_id=179)
- Biomet Microfixation Walter Lorenz Total TMJ Replacement System: Long term Follow up Study (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=90097&c_id=31)

Postmarket Surveillance Studies (522 Studies) of TMJ Implants

The FDA also ordered all TMJ implant manufacturers to conduct postmarket surveillance studies (/medical-devices/postmarket-requirements-devices/522-postmarket-surveillance-studies-program), also known as 522 studies. The FDA ordered the 522 studies over concerns arising from medical device reports (MDRs) submitted to the FDA, including adverse events observed over the expected lifetime of implanted TMJ devices, and timing and reasons for implant revision or replacement. Additional information about these studies is available in our 522 postmarket surveillance studies database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pss.cfm). Studies include:

- Biomet Microfixation Total Temporomandibular Joint Replacement System (P020016)
  - Time to Revision study (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=41&c_id=394)
  - Explant study (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=41&c_id=400)
- TMJ Concepts Patient-fitted TMJ Reconstruction Prosthesis System (P980052)
  - Time to Revision and Explant Analysis study (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=40&c_id=393)
- Nexus CMF TMJ Fossa-Eminence/Condylar Prosthesis Systems (P000035 and P000023)
  - Prospective study (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=39&c_id=3851)
  - Explant Analysis study (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=39&c_id=3852)

TMJ Implant Regulatory History

- 2018: Patient-Led RoundTable at the annual Medical Device Epidemiology Network Initiative (MDEpiNet) meeting (http://mdepinet.org/wp-content/uploads/TMJ-Patient-RoundTable-Briefing-Report_9_25_18.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (PDF)
- 2016: MDEpiNet meeting
- 2011: The FDA ordered all three manufacturers of the four FDA-approved TMJ implants to conduct postmarket surveillance studies to better understand the events associated with the need to remove (explant) TMJ implants and replace (revise) TMJ implants.
- 2007: Government Accountability Office (GAO) published Report on FDA's Approval of Four Temporomandibular Joint Implants
- 2005: The FDA approved the Biomet Microfixation, Inc., Total Temporomandibular Joint Replacement System device (P020016 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020016)).
- 2001: The FDA approved the TMJ Implants, Inc., TMJ Fossa-Eminence Prosthesis (P000035 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P000035)).
- 2001: The FDA approved the Nexus CMF LLC (formerly TMJ Implants, Inc.), TMJ Fossa-Eminence/Condylar Prosthesis System (P000023 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P000023)).
- 1999: The FDA approved the TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis (P980052 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p980052))
- 1998: The FDA published a final rule (https://www.govinfo.gov/content/pkg/FR-1998-12-30/pdf/98-34483.pdf) (PDF) establishing the effective date of the requirement for premarket approval