

FDA approves implant system for transfemoral amputations

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(HealthDay)—The first implant system for transfemoral amputations was approved by the U.S. Food and Drug Administration, the agency announced Friday.

The Osseanchored Prostheses for the Rehabilitation of Amputees (OPRA) Implant System, which has been on the market under a humanitarian device exemption since 2015, is indicated for adults with above-the-knee amputations who cannot use a conventional socket prosthesis. The OPRA Implant System is surgically anchored and integrated into a patient's remaining [thigh bone](#), so that it can connect to an external prosthetic limb, as opposed to conventional leg prostheses that use a socket fitted over the residual limb to secure the device to the leg.

Installation of the implant system is completed through two surgical procedures six months apart. During the first procedure, the surgeon implants a cylinder-shaped fixture into the central canal of the remaining thigh bone. Once tissue has grown to

anchor the fixture and the skin has healed, the surgeon performs the second procedure to attach additional device components to the fixture. The [implant](#) system extends through the skin at the bottom of the patient's residual limb and connects to a prosthesis. Patients must undergo about six months of training and rehabilitation after the second surgery before being fitted with their customized prosthesis.

The approval was based on safety and efficacy data from 65 patients who received the OPRA Implant System. Patient scores on the Questionnaire for Persons with a Transfemoral Amputation improved by 35.1 and 39.6 points on a 100-point scale at two and five years, respectively, compared with their scores with a conventional socket prosthesis. Reported adverse events included infection, mechanical complications, pain, injury, and loosening of the fixture.

The OPRA Implant System was reviewed under the Premarket Approval pathway and is manufactured by Integrum AB in Mölndal, Sweden.

More information: [More Information](#)

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