

Novel leg prosthesis approved

July 16 2015

(HealthDay)—A prosthesis for people with above-the-knee amputations who cannot use a conventional device has been approved by the U.S. Food and Drug Administration.

The Osseanchored Prostheses for the Rehabilitation of Amputees (OPRA) adheres to the leg with fixtures and screws implanted into the remaining [thigh bone](#), rather than fitting into the socket as does a conventional device.

The new device is meant for people who don't have enough of a remaining limb—or have scarring, pain, [skin infections](#) or fluctuating shape of the remaining limb—which make use of a conventional device difficult or impossible.

The OPRA device involves two surgeries to implant the necessary hardware, approximately six months apart. Six months of training and rehabilitation follow, before a user is fitted with a customized prosthesis, the FDA said in a news release.

The new product was designated a Humanitarian Use Device, since it is designed to treat a disease or condition affecting fewer than 4,000 people annually, the agency said. Infection was the most common adverse reaction.

The OPRA device is produced by Integrum AB, based in Molndal, Sweden.

More information: Visit the [FDA](#) to learn more.

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Citation: Novel leg prosthesis approved (2015, July 16) retrieved 26 April 2024 from <https://medicalxpress.com/news/2015-07-leg-prosthesis.html>

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