

I. Specification of type of ankle device for which reclassification is requested.

[860.123(a)(1)]

The current classification types, 888.3100, 888.3110, and 888.3120 should be abandoned. 888.3100 is defunct, based on technology that is no longer viable, and therefore should be eliminated entirely. There are no approved 888.3120 ankle joint replacement devices generally available. Moreover, the import of the decision of 1996 concerning class III ankle devices, Federal Register, Vol. 69 No. 189, is that all ankles are class III, regardless of whether they could or could not meet the definition of 888.3120. All ankle devices, except for those that fall within 888.3110, must go through the same PMA process to be approved by the FDA. Thus, 888.3120 no longer has any statutory probity.

Therefore, the only consideration is whether a subject device meets 888.3110. If it does not, then it is clearly a 'new' class III ankle device. 888.3110 should no longer be used because it cannot produce an ankle joint replacement device that is reasonably safe and effective. As shown in detail in Section III, devices that fit this category have not generally been safe or effective. Thus, the use of 888.3110 should also be abandoned.

Considering the current state of scientific knowledge and clinical experience with ankle joint replacement devices, Endotec proposes a new generic type for ankle joint replacements to replace 888.3110.

- o A partial ankle surface replacement of the superior articulating surface of the talus and the corresponding surface of the tibia for cementless use with a metal tibial component, a metal talar component and an intermediate, congruent, UHMWPe plastic bearing that under compressive loading limits only rotation in the frontal plane between the talar and tibial components and provides only rotation in the lateral plane between the bearing and the talar component by their respective articulating surfaces but where anterior-posterior and medial-lateral translation limitation of the tibia relative to the talus is provided by the malleolar articulations and the ankle ligaments and not by the prosthetic elements.

The device is intended for replacement of the tibiotalar joint in patients with degenerative arthritis of this joint where viable malleoli and ligaments are present.

All other ankle joint replacement devices should be new Class III ankle devices as described in Federal Register, Vol. 69 No. 189.