

IV. Statement of Reasons [860.123(a)(6)]

The reference documents given in APPENDIX C are submitted to support the reasons for the deficiency of the current classification criteria, and to demonstrate a reasonable assurance of safety and effectiveness.

There are five fundamental safety points associated with the description of this reclassification petition. These are:

1. **The stability of the ankle after replacement,**
2. **The stability of the ankle bearing**
3. **The load carrying capability of the ankle replacement**
4. **The undesirability of unnecessary constraint, and**
5. **Fixation.**

Point 1. The stability of the ankle after replacement

References 15 and 20-27 are clinical studies. It may be seen from them that stability of the ankle after replacement is not a problem with the Buechel-Pappas device, which falls within the proposed classification, or the Star device, which has similar stability, constraint and kinematic characteristics. Komistek et al²⁸ and Nelissen et al²⁹ are in vivo kinematic studies, which show essentially normal ankle function after replacement with the B-P device. Garde and Kofoed³⁰ and Magnussen et al³¹ show this to be the case with the STAR device. The stability report by Pappas⁹ is a theoretical analysis of the stability characteristics of the predecessor to the B-P device. It discusses the need of maintaining normal inversion-eversion stability. These studies taken as a whole are adequate in demonstrating a reasonable assurance that the proposed device classification produces a safe ankle joint, with respect to stability, that does not have any new ankle stability problems associated with the relative lack of constraint associated with meniscal bearing joints falling within the scope of the proposed new class.

It is useful to consider a comparison of the stability characteristics of a currently available device, the DePuy "Agility" ankle, that has been classified as class II and given 510(k) clearance, to the B-P device. This comparison is to show that the Agility ankle, which fits 888.3110, and is therefore considered to be reasonably safe and effective, has, in fact relatively poor and risky stability characteristics. The B-P ankle, which the ODE claims fits 888.3120, and therefore cannot be considered to be safe and effective enough to be considered class II, has, on the other hand normal stability properties that appear to be relatively free of risk.

Medial-Lateral: Such stability in the normal ankle is almost entirely provided by the ankle mortise (refer to Fig. a. of APPENDIX A). In the B-P device, as shown in Fig. b., the ankle mortise is retained and thus stability is essentially unaffected.

The Agility ankle, however, resects the mortise as illustrated in Fig. c.. It replaces the mortise with tibial component sidewalls, which are much shallower than the mortise they replace. Due to this shallow engagement and the

large lateral corner radii on its talar component the Agility provides much less medial-lateral resistance than the normal mortise. This is particularly true where inversion or eversion is present. Furthermore the lateral clearance of about 6mm between the talar and tibial components of the Agility provides much greater medial-lateral motion than normal meaning that the medial-lateral stability of the Agility is substantially less than normal.

The resection of the mortise used with the Agility ankle introduces additional risk of medial malleolar fracture as mentioned in the Agility documentation. Further the fibular resection and fusion introduces substantial risk of fibulotalar malunion³²⁻³⁴, a risk not present in the B-P ankle.

In the Agility ankle medial-lateral stability associated with the mortise is replaced by prosthetic constraints. This results in medial-lateral shearing loads being supported by the prosthesis -bone interface rather than by the natural bony structures. Thus unnecessary shearing loads are applied to the prosthesis -bone interface. It is well known that unnecessary loads represent an unnecessary risk to the patient associated with increased possibility of loosening.

Summary: The B-P design provides superior and more normal stability than the Agility. It reduces or eliminates risks associated with mortise resection and fusion in the Agility. Further, it also reduces loosening risk by eliminating unnecessary shearing loads. This is an important characteristic of mobile bearings.

Anterior-Posterior: Such stability is primarily provided in the normal ankle by the ankle ligaments since the tibial retaining arc is relatively shallow. As described in detail in Ref. 9, due to the inclination of the B-P flat plate and the effects of friction the difference in A-P stability between the B-P device and normal is not great. Further this difference is easily resisted by the ankle ligaments, which are well adapted to resist such shear since that is what they normally do.

The Agility ankle has substantial intrinsic A-P stability, much more so than the normal ankle. Thus the Agility is over constrained. It is well known that unnecessary constraints represent an unnecessary risk to the patient associated with increased possibility of loosening associated with unnecessary shearing loads resulting from such constraints.

Summary: The B-P design provides more normal stability than the Agility. Further, it also reduces loosening risk by eliminating unnecessary constraints.

Axial Rotation: Such stability in the normal ankle is almost entirely provided by the ankle mortise. In the B-P device the ankle mortise is retained and thus stability is essentially unaffected.

The resection of the ankle mortise with the Agility produces a loss of stability and increase of risk very similar to that associated with the loss and risk associated with medial-lateral stability.

Summary: The B-P design provides superior and more normal stability than the Agility. It reduces or eliminates risks associated with mortise resection and fusion in the Agility. Further, it also reduces loosening risk by eliminating unnecessary shearing loads. This is an important characteristic of mobile bearings.

Inversion-eversion: Such stability in the normal ankle is primarily intrinsic. Ankle ligaments play a role where inversion-eversion torque on the ankle is present. Such stability is discussed in detail Ref. 9. Since the medial-lateral width of the B-P talar component is the same as the natural talus this stability mode is unaffected.

The talar component of the Agility ankle is, however, much narrower than the normal talus. Further, due to the large lateral corner radii used on the Agility the width of the articular surface of the talar component is considerably less than the reduced width of the component itself. These large corner radii are used in order to avoid sharp edge contact during inversion-eversion. Thus inversion-eversion stability is greatly reduced. The implications of this are discussed in Ref. 9. Inversion-eversion ankle injuries are very common. Thus a substantial reduction in such stability poses a substantial risk to the patient since it can much more easily produce overloading of the ankle ligaments and therefore ankle sprain or strain. Figures b. and c. provide a graphic comparison of the inversion-eversion stabilities for the Agility and B-P ankle devices.

Summary: The B-P design provides superior and more normal stability than the Agility. Further it reduces risk of ankle strain and sprain by providing normal rather than much less than normal inversion-eversion stability.

Point 2. The stability of the ankle bearing

The position that the FDA originally took with regard to mobile bearings, based on what they probably knew at the time, appeared to be prudent. Certainly, we thought so at the time. It was our feeling that mobile bearings introduced bearing stability issues that could only be adequately addressed by a clinical trial.

Viewed in hindsight, from a base of knowledge available today, the position appears to have been one that probably produced more harm than good. Fixed bearing knees, including those with either inadequate mobility or excessive contact stress could be sold based on a 510k submission. Mobile bearing knees, which were capable of providing both mobility and congruity, could not. They could only be sold after a long and expensive clinical trial and PMA submission. Thus, the effect of the FDA position on mobile bearings was to discourage the use of designs that were capable of solving a fundamental dilemma of knee designers. The dilemma of finding a compromise between the conflicting requirements for mobility and congruity in fixed bearing knees. This position greatly inhibited the development and use of a superior knee concept and thus encouraged and sanctioned the use of knees with a serious fundamental flaw.

Wear is the most serious long-term complication in knee replacement. If the FDA had allowed the mobile bearing LCS to be sold under a 510k and had the FDA used a policy of insisting that knees could only be sold if they were scientifically sound, fixed bearing knees would not have been used as extensively as they are today. As a result, many thousands of patients with knees that failed due to overloading of their articulating surfaces would have been spared the disastrous results of such common replacement knee failure.

The fallacy of a position that requires a PMA approval for a mobile bearing, but allows a 510k clearance for fixed bearing designs, is particularly clear in the case of ankle prostheses. The problem of overloading is even more acute than in the knee since the ankle is very much smaller than the knee yet has loads of very similar magnitude¹⁸. This is one of the most important reasons for high failure rates in ankle replacement. Due to excessive failures, ankle replacement has fallen in to general disrepute with orthopaedic surgeons who normally use fusion as the preferred treatment method.

The most serious risk associated with mobile bearings is the risk of bearing dislocation or subluxation. Although in knees such stability issues have been a problem, they have been solved. Such problems have not been seen with current mobile bearing ankles. History indicates, that for knees, the risk associated with overloading is higher than risk associated with bearing stability and mobile bearings seem preferable to fixed bearings. This is much more

true for the ankle where the risks of overloading are even higher and the risks associated with bearing stability are very much less⁹.

The study by Kewish et al²⁰ is an unpublished paper on the results of part of a clinical study of a few hundred patients on the predecessor to the current B-P device. This study did disclose some problems with bearing subluxation. These problems were, however, secondary to talar necrosis and collapse, a fixation design problem. This problem is also discussed in Buechel et al¹⁵. Correction of this fixation problem in the current B-P device has eliminated this subluxation¹⁵. From Refs. 15, 23 and 24 one can see that it is not a problem with either the B-P or STAR mobile bearing designs.

Point 3. The load carrying capability of the ankle replacement

The computation of the contact stress in the intermediate ankle bearing of the B-P device is given in APPENDIX B. It may be seen that the stress of 5 MPa is well below the manufacturers recommended limit of 10MPa and far below the usual stresses seen in knee devices as given in Refs.10-12.

Point 4. The undesirability of unnecessary constraint

This issue is discussed in Section III. That the B-P device does not have unnecessary constraints is demonstrated in Ref. 7.

Point 5. Fixation

Buechel et al¹⁵ and Kewish et al²⁰ demonstrate that tibial fixation in the current B-P ankle device is safe. In Ref.21 a study of 237 cases shows a low incidence of lucent zones and a low (2%) tibial component-loosening rate for cementless devices. The same is true for the 90 cases of Ref. 15 except that no clinically loose devices were observed on revision and no component was revised for loosening. Both the predecessor device and the current device use a short central peg of similar dimensions to augment fixation of the tibial plate. Details on the tibial fixation results are given in Ref. 15. These results show that the tibial component is safe for cementless use.

Fixation failure of the talar component was unacceptably high for the predecessor device primarily due to talar subsidence as described in Ref. 15. It is, however, acceptable for the current device that uses a dual fin rather than a single fin fixation to augment fixation of the talar onlay. The rationale for this change is discussed in Ref. 15. The use of dual fins minimizes the intrusion into the blood supply to the talus. An onlay greatly reduces talar bone loss on implantation allowing the preservation of much subcondral bone on the proximal talus. No talar component of the current type has been revised for loosening although one case of partial talar collapse in the 50 cases studied has been observed. Details on the talar fixation results are also given in Ref. 15. These results show that talar component is acceptably safe for cementless use.

Summary of the five points:

The first four points have been incorporated into the classification description. The description has been tightly drawn so as to include all elements which best current information indicates are necessary to produce a device comparable to that of Ref. 15 in safety and efficacy. Since there are many ways adequate fixation can be achieved it is

felt that the last point on fixation is best handled by special controls. Such controls can be developed after reclassification so as to allow the evaluation of other devices, which fall within the new reclassification definition.

Finally comparing the results of Ref. 15 and 20-27 with those of Refs 3-6, 33 and 34 one may see that a replacement joint fitting this description is at least as safe as devices that are, or were, commercially available. For example compare Table 2 of Ref. 15 with Tables I and II of Ref. 3. It may be seen that the survivorship of the meniscal bearing designs of Ref. 15 for moderate length use of 5-6 years is at least comparable to the short-term survivorship of the devices of the type used to justify the class II designation of 888.3110.

Comparing the results of Ref. 15 and 20-27 with those discussed in Ref. 3 for arthrodesis demonstrates that the risks of associated with replacement that fit the description appear acceptable, particularly when the improved functional performance of replacement is considered. Kofoed and Stürup²² in their long-term comparison of arthroplasty and arthrodesis draw a similar conclusion.