

### III. The Basis for Disagreement with the Present Classification [860.123(a)(5)]

The current FDA classification system of 888.3110 and 888.3120 for ankle devices is deficient and antiquated. It was developed almost twenty years ago based on relatively short-term clinical trial data which later experience has shown, presented an overly optimistic picture of the performance of the designs used to justify the classification criteria.

Buechel and Pappas describe the state of the art in ankle more than twenty-five years ago in a talk given before the ninth annual meeting of the Foot and Ankle society<sup>1</sup>. They conclude that ankle replacements of the period are unsatisfactory. Not much has changed as can be seen from the recent surveys of Buechel<sup>2</sup> and Nuefeld and Lee<sup>3</sup>, which draw essentially the same conclusion for most designs. The exception is mobile bearing ankles that were introduced in 1978.

The FDA based its current classification rationale primarily on the relatively early results of the clinical performance of the Oregon, UCI, and Beck-Stefee (Conaxial) devices as described in the Federal Register Vol. 47, No. 128 Friday, July 2, 1982, p 29070, Section 888.3110. Later clinical studies, however, demonstrate that these early results presented an overly optimistic picture of the expected clinical performance of these devices. Wynn and Wilde conclude that the Conaxial ankle should not be used<sup>4</sup>. Groth and Fitch draw a similar conclusion for the Oregon ankle<sup>5</sup>. Kitoaka et al show that the early optimism for the Mayo ankle mentioned in the 888.3110 is unwarranted<sup>6</sup>. Tables I and II of Ref. 3 provide an excellent comparison of the early promising results on which the current classification is based with the later disastrous results.

The orthopaedic community has now abandoned all of these early designs. Most of these early devices that fell within 888.3110 were overconstrained. Raikin et al<sup>7</sup> and Matejczyk and Greenwald et al,<sup>8</sup> discuss the problems of overconstraint. 888.3100 and 888.3120, particularly as interpreted by the FDA, accept and encourage overconstraint. Thus, the recommendations of 888.3110 have failed. It has been shown not to produce reasonably safe devices. For this, and the other deficiencies cited, the class II designation provided by 888.3110 should be abandoned.

The 888.3110 and 888.3120 have several additional major deficiencies.

- They are not definitive. Since a device can limit motion in one plane and not another it is possible for such a device to fall within both 888.3110 and 888.8120.
- The FDA interpretation of these definitions has accepted and encouraged the use of overconstrained devices. The current FDA rationale requires the use of unnecessary mechanical constraints where viable natural constraints are present. It is preferable to use natural, rather than mechanical, structures to provide needed function since such use reduces risk associated with loosening and wear without sacrificing the functional characteristics of the joint after partial prosthetic replacement. We agree that the maintenance of joint stability is important. We feel, however, that where possible such stability should be provided by the natural structures where they are available and not mechanically.
- Further the current classification criteria allow unnatural rotation in the frontal plane, which produces less than normal inversion-eversion stability increasing risk of ankle ligament injuries. This issue is discussed by Pappas.<sup>9</sup>

- The current classification also allows the use of incongruent articulations, which unnecessarily increase risk associated with wear. Pappas et al<sup>10</sup> in their paper on contact stresses, and Wright and Bartel<sup>11</sup> and Bartel et al<sup>12</sup> in their papers on surface damage and conformity, discuss the issue of the load bearing capacity of plastic and metal joint articulations. Engh<sup>13</sup> and Collier<sup>14</sup> are typical of many reports of the problems resulting from overstressed contact in knees. References 2 and 15-17 discuss the implications of the inadequacy of incongruent contact in ankle devices. All ankle and knee articulations that we, or any one who has published their results, have examined show that contact stresses in incongruent ankle replacements is expected to be excessive. Such a result is expected since it is well known that excessive contact stresses are typical in incongruent knees and since although the loading in the ankle<sup>18</sup> is similar to, or greater than in, the knee the ankle is much smaller. Thus, one would expect the situation in ankle devices to be worse than that in the knee. We know of no credible evidence that incongruent ankle contact stresses are not excessive. As a result the device type that we request reclassification for must be congruent.
- Wynn et al<sup>4</sup>, Groth and Fitch<sup>5</sup>, and Kofoed<sup>19</sup> demonstrate that even congruent ankle devices that have unnecessary constraint have a high risk associated with them. Thus, the device type that we request reclassification for must also allow the natural retained structures to function where they are present and viable thus eliminating or reducing undesirable and unneeded loading of the fixation–bone interfaces and thus reducing risks associated with loosening.
- The current classification definitions, or special controls, ignore the issue of adequate fixation. Clinical experience has shown that proper fixation is an important element of risk management. Buechel et al<sup>15</sup> and Koblisch et al<sup>20</sup> demonstrate that fixation is an important element in clinical success. These studies show that unexpected fixation problems that may not develop in relatively short-term clinical use can significantly degrade device performance. Thus it seems proper to include fixation elements as well as constraint elements in evaluation criterion. For example if the fixation criteria were not included in the definition or special controls the predecessor device of Ref. 21 the LCS NJ ankle, might be granted 510(k) status. This early design is clearly not as safe as its replacement the B-P ankle<sup>15</sup> and thus should not be used.

Some of the references and studies supporting these statement are given and also discussed in section

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