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Summary of Safety and Effectiveness

This statement regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Bioplate Fixation System is manufactured of commercially pure titanium and a titanium 6A1-4V ELI alloy, materials that have been implanted safely for many years. These materials are recognized as acceptable for implantation purposes through device classification (for example, see 21 Code of Federal Regulations, sections 888.3030.)

The plates are substantially equivalent in construction and design to the predicate devices manufactured by Howmedica, Medicon, Inc. , KLS and W.L. Lorenz. The screws are manufactured of a titanium alloy that is substantially equivalent in design to the predicate devices.