K963242

510(k) Summary

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Device: Duracon® Femoral Posterior Spacer

The Duracon® Femoral Posterior Spacer is intended to be used with the femoral components of the Duracon® Total Knee System (reference premarket notifications K910235, K920034, K932070, and K954138) to augment bone loss in the area of the posterior condyle of the femur. Posterior bone loss that requires augmentation by spacers may be noted in primary or revision total knee arthroplasty cases.

The Duracon® Femoral Posterior Spacer is cemented to the femoral component, and then the spacer-femoral component assembly is cemented into place.

The Duracon® Femoral Posterior Spacer is substantially equivalent to several other legally marketed devices. Examples of these are listed below:

1. Duracon® Total Knee System Distal Femoral Spacers (K915512) - Howmedica
2. Duracon® Total Knee System Distal-Posterior Femoral Spacers (K915512) - Howmedica
3. Kinemax® Plus Superstabilizer Total Knee System Femoral Posterior Spacers (K904208) - Howmedica
4. Series 7000 Total Knee System Femoral Posterior Spacers - Osteonics Corporation
5. Genesis Total Knee System Femoral Posterior Spacers - Smith & Nephew Richards
6. Coordinate Total Knee System Femoral Posterior Spacers - DePuy

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