

510(k) SUMMARY

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Name of Company: Corin Medical Ltd.
The Corinium Centre
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United Kingdom

Name of Device: The C-Fit Femoral Hip System

Device Description: A femoral hip system consisting of standard and long stem options with or without calcar collars, plasma sprayed either proximally or five eighths of stem and for use with or without a PMMA cement centralizer. The devices are used to resurface the femoral hip joint and reconstitute function following the degenerative effects of osteo and rheumatoid arthritis, post trauma disease effects, avascular necrosis and septic or aseptic total hip revision. The femoral stems are manufactured from cobalt chrome alloy. The cobalt chrome plasma spray coating provides an increased surface roughness to act as key for mechanical interlock with PMMA bone cement. The stem devices may be used with any one of a range of previously cleared Corin cobalt chrome modular heads, bipolar or uni-polar modular devices. The C-Fit plasma sprayed femoral components are intended for use with bone cement only.

**SUMMARY OF SUBSTANTIAL EQUIVALENCE
AND SAFETY AND EFFECTIVENESS**

The C-Fit Femoral Hip system is a modification of the previously cleared V.S.P. (now called C-Fit stem) Hip system, manufactured by Corin Medical Ltd. The original V.S.P. (now called C-Fit stem) stem is manufactured from titanium alloy with a cobalt chrome plasma spray coating applied. This submission extends the range to include a cobalt chrome stem with cobalt chrome plasma spray coating and long stem options. The C-Fit cobalt chrome stem without coating is previously cleared for sale for use with cement. Corin, additionally, claims substantial equivalence to the Mallory/head system from Biomet, with the specific reference to plasma sprayed long femoral stems.

This submission is supported by extensive mechanical test data confirming the device's safety and effectiveness. The device has been in clinical use outside the U.S. for approximately ten years and no significant post-operative problems have been reported.