To Whom It May Concern:

OrthAlign is pleased to announce FDA 510(k) clearance for Lantern® Hip.

Lantern Hip is a handheld technology for total hip arthroplasty (direct anterior approach with the patient in supine position), and is the latest addition to the Lantern platform, joining existing applications for total knee, revision knee, and partial knee arthroplasty.

Lantern Hip builds upon the legacy of HipAlign® with enhanced technology and usability. Next-generation accelerometers and gyroscopes offer orthopedic surgeons a streamlined workflow, real-time navigation for cup positioning, and restoration of leg length and offset. The technology enables individualized cup positioning compared across multiple planes, including the functional pelvic plane, anterior pelvic plane, and coronal plane, with live pelvic tracking. Lantern Hip includes instrumentation to make the technology compatible with most implant systems.

A Lantern Hip procedure requires:

- Lantern Hip Navigation Unit (502000-01)
- Lantern Hip Instrument Set (502001-01)

Prescription Only (Rx): Federal Law restricts this device to sale by or on the order of a physician.

Lantern® Hip is only to be used by a trained licensed physician. Please refer to the Lantern® Hip Instructions for Use (001379) for complete important safety information.

The Lantern® Hip Navigation Unit (502000-01) is currently not CE marked and unavailable for purchase or use in the European Union.

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