

ASX Announcement

Spinal Cage FDA Submission Update – Supplementary Announcement

SYDNEY 4 AUGUST 2023– Allegra Orthopaedics Limited (**Allegra**) (ASX: AMT) provides a summary of the additional information requested by the United States Food and Drug Administration (**FDA**) under the 510(k) pathway in respect to the Sr–HT–Gahnite Spinal Cage Device (**Spinal Cage**) submission:

1. Chemical characterisation and toxicological risk assessment
2. Animal performance testing
3. Sterilisation, packaging, and shelf-life validations

The FDA have requested additional information to answer specific questions related to these areas, which is an expected part of the review process. Allegra is gathering available data and expects to send our formal response to the FDA within the next 2-3 months.

This announcement should be read in conjunction with the Spinal Cage FDA Submission Update ASX announcement dated 16 August 2023. Allegra will continue to update the market on any further developments of the Spinal Cage FDA submission.

This announcement has been authorised for release by the CEO of Allegra.

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ABOUT ALLEGRA ORTHOPAEDICS:

We aim to help bring the freedom and happiness of pain-free movement to people’s lives. We achieve this through providing the best possible solutions for patients, from world-wide industry leading orthopaedic products through to Australian innovations. Allegra’s principal product, the Active Total Knee, has significantly improved the quality of life for many people and remains a focused product line. Allegra is also the exclusive distributor of Waldemar Link GmbH & Co. KG products in Australia. Link consists of a range of complex lower limb, hip and knee replacements, including oncology solutions. The Link products add to Allegra’s well-developed range of products for distribution from international suppliers covering all specialties from foot and ankle to upper limb. The company is pleased to continue to build upon its extensive portfolio of patents. It has strong research relationships with universities, companies and surgeon inventors.

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