



## **ASX/MEDIA RELEASE**

### **FIRST SALES IN CONTINENTAL EUROPE ASDM ACTIVE KNEE AWARDED CLASS III CE MARK**

**Sydney, 2<sup>nd</sup> December 2009** - Leading Sydney medical device design, manufacturing and marketing company, Advanced Surgical Design and Manufacture Limited (ASDM) (ASX: AMT), announced today:

- granting of Class III CE Marking for its Active Knee total knee replacement system, and
- appointment of an exclusive distributor for Greece

#### Class III CE Mark Approval

The Active Knee, ASDM's flagship product, has been granted the higher Class III CE Mark Approval. This is the highest classification for this type of device and is above the Class IIb rating previously held.

This means that the Active Knee is fully compliant with the revised EU Medical Device Directive (MDD), requiring that joint replacements meet the Class III rating. ASDM is now in a position to intensify its sales and distribution into the European Market. ASDM understands that a number of competing knees have failed to satisfy this new regulatory standard and are now having to be withdrawn from European sale.

In addition to the Class III approval, the Therapeutic Goods Administration (TGA) has reissued ASDM's Conformity Assessment certificate for Australian regulatory approval.

#### Further European Representation

Leveraging off the Class III CE Mark Approval, ASDM's UK distributor has appointed Medical Developments of Athens as exclusive distributors in Greece as a first step towards broader European representation. The Active Knee is being supplied to 6 hospitals already and the first knees have been successfully implanted.

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## About ASDM

ASDM designs and manufactures medical devices. Its principal product is the Active Knee, a prosthetic implant of which more than 5,000 have been implanted. This product is supported by a range of Orthopaedic accessories and surgical tools and other Orthopaedic products.

Since 1994 ASDM has provided a highly effective integrated service to surgeons building on its strengths in design and engineering. Core capabilities that underpin this service are integrated design and engineering, regulatory/compliance competency, manufacturing, distribution and customer service.

The company has built an extensive patent and product development portfolio through collaborative research relationships with universities, companies and surgeon inventors that extends beyond orthopaedics. These collaborations are yielding promising projects in several specialities with strong prospects for commercialisation over the next few years.

For more information, please visit [www.asdm.com.au](http://www.asdm.com.au)