Eucomed statement

Unsafe and Ineffective Devices Approved in the EU that were Not Approved in the US

U.S. Food and Drug Administration (FDA), May 2012

The European medical technology industry association Eucomed holds the opinion that the FDA report "*Unsafe and Ineffective Devices Approved in the EU that were Not Approved in the US"* is inaccurate and its conclusions placed out of context. The report contains multiple factual errors and the conclusions are framed is such a way that do not reflect the current regulatory reality in Europe. Therefore, being factually incorrect, one must conclude that the motivation of the report is most likely based on political reasoning.

The FDA report compares the US and EU system on five criteria (see picture below), of which four are inaccurately described.

Box 1. Regulation of High-Risk Devices in the US and EU

	US	EU
Standard for approval	Safety Effectiveness: proof of actual benefit to patients	Safety Technical performance, not benefit to patients
Evidence required	Valid clinical trials—generally randomized and controlled	Limited data, which may be laboratory testing, literature reviews or small clinical trials
Approval granted by	Central regulatory authority: FDA	Notified bodies: private, for-profit organizations chosen and hired by the manufacturer. Approval by any notified body authorizes marketing throughout EU
Transparency of approval decisions	Approvals and their evidentiary basis disclosed to public	Neither approvals nor evidentiary basis disclosed to public
Post-approval reporting requirements and transparency	Side effects and recalls must be reported to FDA and are publicly disclosed on its website	Side effects are reported to notified bodies but not to any government authority. Reported side effects and recalls are not publicly disclosed.

Standard for approval

The FDA report states incorrectly that in Europe the standard for approval is based on technical performance, not benefit to patients. In Europe a positive risk-benefit profile for patients is demanded and is part of the regulatory framework.

Evidence required

The FDA report states incorrectly that in Europe limited data is required. In Europe appropriate clinical evaluation of clinical data is required for all medical devices before they are marketed. In particular, for both implantable devices and devices in Class III, the clinical evaluation must be based on data obtained from clinical investigations unless it is justified to rely on existing clinical data.

Approval granted by

The FDA report states incorrectly that [all] notified bodies are private, for-profit organisations. In Europe there are private notified bodies but there are also many who are run by governments. All notified bodies in Europe are specifically chosen, designated and under the continuous supervision of Competent Authorities (i.e. government).

Post-approval reporting requirements and transparency
The FDA report states incorrectly that in Europe side effects and recalls are not reported to any government authority. In Europe the side effects and recalls must be reported to the authorities and are collected in the EUDAMED database which is accessible by all EU member states.

The criteria **Transparency of approval decisions** states correctly that neither approvals nor evidentiary basis is disclosed to public in Europe. Eucomed has proposed to change this in the current Revision of the Medical Devices Directive and the European Commission has indicated to do so.