MAQUET Cardiovascular Announces U.S. Food and Drug Administration Panel Votes To Reclassify Intra-Aortic Balloon Pumps To A Class II Designation In Certain Indications

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WAYNE, N.J., Dec. 13, 2012 /PRNewswire/ -- MAQUET Cardiovascular, the leader in intra-aortic balloon (IAB) therapy, today announced that the Circulatory System Devices Panel of the U.S. Food and Drug Administration (FDA) recently voted to support the Agency's reclassification of intra-aortic balloon pump (IABP) devices for certain indications to Class II (general controls and special controls) from Class III (general controls and pre-market approval). Those indications that received a recommendation to be reclassified to a Class II designation include acute coronary syndrome, complications of heart failure of both ischemic and non-ischemic etiologies, and cardiac and non-cardiac surgery.

According to the FDA and its panel of physicians and representatives, this recommendation was based on 40 years of extensive clinical experience and extensive literature, which support the hemodynamic effects and the devices' safety and effectiveness in the aforementioned patient populations.

"As the leaders in intra-aortic balloon (IAB) therapy, we are proud that the proven nature, tremendous volume of clinical evidence and clinical utility was validated by both the FDA and members of the panel and that IABPs have set the bar for other devices in this category," said Luca Lombardi, M.D., Chief Medical Officer, MAQUET Cardiovascular. "IAB therapy has been trusted by physicians for decades, and we believe this panel vote is a testament to the importance and utility of this treatment as the standard first-line therapy for patients requiring hemodynamic support."

"MAQUET applauds the FDA panel for recognizing the safety and efficacy of IAB therapy and its benefit for patients in need," said Raoul Quintero, President and CEO, MAQUET Medical Systems USA. "Securing Class II status for IABPs will enable us to rapidly bring new technologies to market so that physicians may continue to deliver the most advanced technology in hemodynamic support to their patients '/>"/>

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