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Korean FDA clears Mazor's robotic platform

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Singapore: The Korean distributor of Mazor Robotics, BR Holdings, received marketing clearance from the Korean Food & Drug Administration (KFDA) to market Mazor's Renaissance system. Israel-based Mazor Robotics is a developer of innovative surgical robots and complementary products. Renaissance is its surgical guidance system for spine procedures.

BR Holdings is a leading distributor of robotic surgery technologies and instruments in Korea.

"Korean spine surgeons performed 120,000 cases in 2008, reflecting 18 percent annual growth from 2003. Per capita, it is the second largest spine surgery market globally, and the country adopts new technologies with enthusiasm," said Mr Ori Hadomi, CEO of Mazor. "As an example, the Korean healthcare system currently supports 36 da Vinci surgical robots. We expect Korea to be a very strong market for our surgical robots and serve as a gateway to the Asia Pacific region, as it has in the past for other robotic technologies."

It is typical for the local distributor to take responsibility for securing Korean regulatory clearances, and BR Holdings is also presently pursuing reimbursement. In partnership with BR Holdings, Mazor will immediately begin to market Renaissance to establish early adopters and build local clinical experience.