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## **BIORTHEX RECEIVES ANOTHER APPROVAL FROM CANADIAN TPD TO BEGIN A CLINICAL STUDY ON ACTIPORE™ ACF**

**Montreal, CANADA, August 20, 2003** – Biorthex Inc., a medical device company specializing in spine, is pleased to announce the second conditional approval obtained this year from the Therapeutic Products Directorate (TPD) of Canada for the initiation of a Canadian clinical trial this time for its *Actipore™* ACF Anterior Cervical Fusion device, indicated for patients suffering from a degenerative disc disease (DDD) in the cervical spine.

Mr. Benoit Sicotte, President and CEO of Biorthex stated: "This is the fourth approval received in the past few months from North American regulatory agencies, which opens the way to fulfilling the tremendous potential of our *Actipore™* technology and demonstrates our company's team efforts in submitting the necessary documents and data in order to obtain clearance."

The *Actipore™* ACF device is indicated for patients suffering from pain associated with DDD in the cervical spine. This study will be a randomised, prospective, multi-center clinical trial designed to determine the safety and efficacy of the *Actipore™* ACF interbody fusion device.

"We are now in the position to begin two combined Canada/U.S. clinical trials, one for our cervical intervertebral fusion device and another for our lumbar intervertebral fusion device", added Mr. Sicotte.

Through *Actipore™*, Biorthex holds a unique ultra porous biologically and biomechanically compatible material, with a porous structure consisting of interconnected passageways, which permits long term bone cell integration and survival throughout the devices. This exclusive technology platform has similar mechanical properties to bone, resulting in load sharing, rapid tissue ingrowth and eliminating the requirement for additional bone graft material, thus reducing the time of surgery, the risk of complications and preventing graft site morbidity.

Biorthex Inc. is a medical device company that designs, develops, manufactures and markets innovative products for the surgical treatment of spinal disorders.

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### **For information:**

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