

asc

ADVANCED
SURGICAL
CONCEPTS

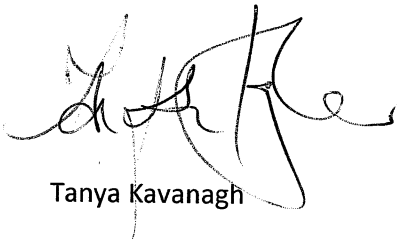
26th January 2010

To Whom It May Concern

RE: ASC QUADPORT DEVICE

The ASC TriPort and the QuadPort are members of the same product family, consisting of the same materials and same intended use. In accordance with the FDA Guidance entitled "Deciding When to Submit a 510K for a Change to an Existing Device," the QuadPort is considered to be a minor modification to the legally-marketed ASC TriPort (K073719). The minor design modifications made to the TriPort device to create the Quadport do not significantly affect the safety or effectiveness of the QuadPort. According to the FDA Guidance, a new 510K is not required to legally market the Quadport device.

Further details are available upon request.



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