

STATEMENT ON SUBSTANTIAL EQUIVALENCIES: There are three substantial equivalencies between the SABER and other products on the market. 1) Each opens a donor segment without the use of scissors. 2) Both devices involve a piercing action vs a cutting action. 3) The devices are also designed for safety and effectiveness.

STATEMENT OF SAFETY AND EFFECTIVENESS: A statement regarding the safety and effectiness of the SABER will be provided to any person who may inquire.