Fees and Timeline

SWISS MEDTECH

	USA	EU
Fees	Class II (510k submission): Standard fee: $ 21‘760, Small business fee: $5‘440 Class II (De novo request): Standard fee: $ 145‘000, Small business fee: $36‘000 Class III (PMA application): Standard fee: $ 483‘000, Small business fee: $120‘000	No fee structure! NB demands payment for work delivered Payment ranges from €30‘000 to 1 mio.
Timeline	Class II (510k submission): Timeline: 90 d, average time needed: 177 d Class II (De novo request): Timeline: 150 d, average time needed: 394 d Class III (PMA application): Timeline: 180 d, average time needed: 243 d	No timeline! „It takes as long as it takes“ Timeline ranges from 6 to 48 months (mostly 18 to 24 months)

FDA vs. CE

SWISS MEDTECH

	USA	EU
Fees	Reasonable and fixed	High and unpredictable
Timeline	Reasonable and predictable	Highly variable and unpredictable
Support for innovation	High (Pre-submission, Break-through devices program)	None
Market size	Biggest world market	2nd biggest world market
Market proximity	On another continent	Close and well known
Market access	Difficult and very expensive	Difficult and expensive, different payment schemes
Remarks	Regulation follows technological advances. Centralised role of FDA leads to more uniformity and transparency in the regulation of medical devices.	Regulation is rigid. Decentralised approach with national authorities and private sector NBs can lead to inconsistent interpretation of the regulations.