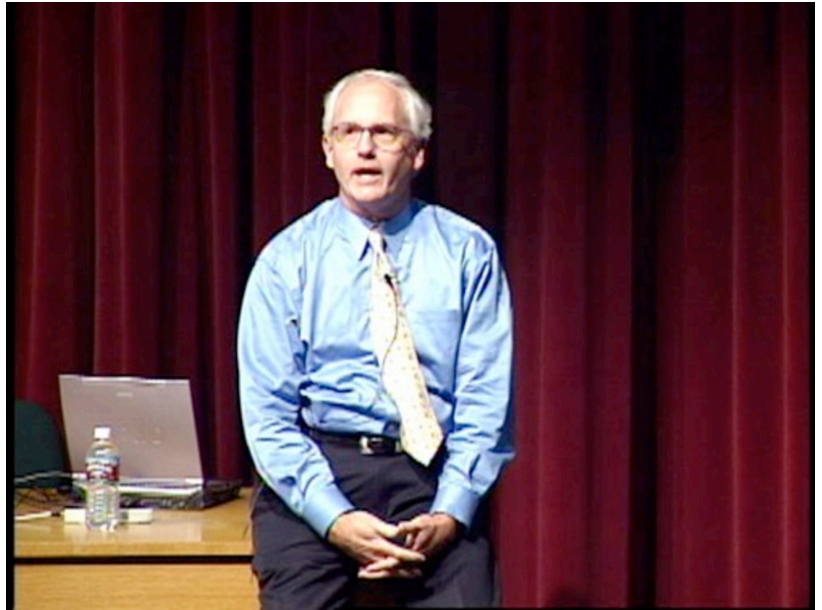


URL: <https://stvp.stanford.edu/blog/videos/testing-medical-devices-and-overcoming-fda-hurdles>

Yock talks about his company and his experience with the FDA and a Norwegian government official who approved their technology very quickly.



## Transcript

So we put together this company and this was the first scanner that we developed and it had the usual hosts of technical problems but basically, within about a year's worth of engineering.. we had a prototype that we thought was good enough to test and so I called up the FDA.. Is anybody here from the FDA? I have the experience of telling a story with the head of the device panel in the audience and I didn't know about it.. But here's my rift on the FDA.. So I called up the FDA and tried to get a feeling for how long it was going to take to test this device and the answer seems to be.... It was clear the answer was longer than a year to get it tested.. And so I thought about that for a while.. That didn't seem very good and I called a friend of mine in Europe, in Norway actually, a cardiologist there and I said, "You know, just out of curiosity what would it take to test us in Norway?" And then he said, "Well I don't know but I'll find out.. I'll call the person who makes that decision." So at that time anyway, there was a person in the Norwegian government who made the decision and my friend called me back the next day and said, "It's okay." And I said, "What do you mean?" He said, "It's okay." And so two weeks later, we went over to Norway and did the.... These are the first human images from inside a blood vessel with a catheter..

This was incredibly fun for me.. I was driving and I brought these images back and showed them that Dr.. Simpson and Dr.. Fogarty, their comment looks a little bit like a hurricane off the coast of Miami to us but....