Medtronic: FDA panel rejects heart catheter(2)

Medtronic Inc. says a panel advising the U.S. Food and Drug Administration has concluded that an experimental catheter from the medical device maker poses a potential health risk that outweighs its benefit to patients.

The company is asking the FDA to approve the device for atrial fibrillation, which causes the heart's upper chambers beat rapidly and ineffectively.

The catheter uses extreme heat to correct irregular heartbeats.

Medtronic said Thursday that the FDA's Circulatory Systems Devices advisory panel voted against the device.

It said a majority of the panel's members concluded from clinical trial data that there isn't a reasonable assurance that the catheter is safe to use.

The panel's recommendation isn't binding, but will be considered by the FDA when it reviews Medtronic's request to bring the device to market.