FDA 510(k) Premarket Notification

**CLEARED**

# K042096 MISONIX INC. SONATHERM 600 ULTRASONIC LESION GENERATING SYSTEM

Jan 26, 2006
540 days to decision

K042096 · Product code: **NTB** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k042096/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Ablation, Ultrasound And Accessories (NTB) |
| Date received | Aug 4, 2004 |
| Decision date | Jan 26, 2006 |
| Days to decision | 540 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Misonix, Inc.** |
| Location | Farmingdale, NY, US |
| Contact | RONALD R MANNA |
| Website | http://www.misonix.com/ |
| 510(k) history | 17 submissions · 17 cleared · 1998-2022 |

Misonix, Inc. specializes in ultrasonic surgical and wound care devices, with a manufacturing facility in Farmingdale, US. The company developed core technologies for minimally invasive surgical applications and therapeutic ultrasound systems. Misonix received FDA 510(k) clearances from total submissions between 1998 and 2022. All cleared devices fall within the General & Plastic Surgery category. The company's regulatory record reflects sustained focus on ultrasonic surgical aspirators, lesion-generating systems, and ultrasonic wound care platforms. The company is inacti...