THIS FORM REPLACES THE "SUBSTANTIAL EQUIVALENCE DECISION MAKING DOCUMENTATION" FOR EXEMPT DETERMINATIONS.

Date:

Exempt Device Review Form
K

Contact:

Company Name:
Address:

510(k) Number:
Tradename:
Dated:
Received:

Product Code: **Class:** **FR Classification No.:**

Manufacturing Address:

Common Name:

Intended Use:

	Exempt Device Decision Table	Yes	No
1	Does the device description match the exempt definition?	Go to 2	Go to 5
2	Does the device involve new technology?	Go to 5	Go to 3
3	Does the device have new indications?	Go to 5	Go to 4
4	The device is exempt from 510(k).	Prepare Exempt Letter	
5	Device is **not** 510(k) exempt, perform a normal review.		