**Medical Device Model Recall Press/News Release Template**

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*Note: Text in bold should be modified to reflect appropriate company information*

**Company Name**Issues Nationwide Recall of**Product(s) Name(s)**

FOR IMMEDIATE RELEASE: **Date of News Release  
Company Address  
Telephone/Company Website**

On **date of recall initiation, Company Name**initiated a nationwide recall of **quantity and name of product(s)**. The **product(s)** have been found to **describe problem**, which **has/potentially**could result in **describe public health risk**.

**State if there is a related recall.**

Consumers who have **product(s)** should **stop using/return/replace/throw away/contact their doctor, etc**.

Recalled**Product(s) was/were**manufactured from**date**to**date**and distributed from **date** to**date**.

The following **styles/models/UDI/ID numbers, (etc.)**have been recalled:

Name of Product

UDI

Model(s)

Serial Number(s)

Quantity

Product(s) can be identified by **provide additional details about how product(s) can be identified**.

**Company Name**voluntarily recalled **product** after becoming aware of**fill in**. **Company Name**has notified the FDA of this action.

**Brief explanation of what is known about the problem, including the number, type and status of any confirmed injuries--for example, “No injuries have been reported to date.”**

**Company Name** is notifying its distributors and customers by **describe method**and is arranging for**return/replacement/retrofit, etc**. of all recalled**product(s)**.

**Company Name distributed product(s)** to **describe type of outlets, states/ geographical area**.

Consumers with questions may contact the company via telephone at**provide 1-800 number**between the hours of **x and x (time zone)**. Consumer may also contact the company via e-mail at **e-mail address**.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

* Complete and submit the report **Online**: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
* **Regular Mail or Fax**: Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088[](https://www.fda.gov/safety/industry-guidance-recalls/medical-device-model-recall-news-release) to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178[](https://www.fda.gov/safety/industry-guidance-recalls/medical-device-model-recall-news-release)