



(benefit\* risk\*) NEAR device\* ✕ ➔

## SmartSearch Filters

FDA Regulation (21 CFR/Guidance)

CFR (15) ▼

FDA Agency (CBER/CDRH/CDER)

Select value ▼

## FDA Search Results Shown Below

[FDA Regulation (21 CFR/Guidance) ="CFR"]

15 results for '(benefit\* risk\*) NEAR device\*' ⬆

Click to Sort SmartSearch Results ▼ ⬆



[Subpart D - De Novo Classification](#)  
**Procedures for review of a De Novo request.**  
**Sec. 860.240(c)(1)**

[Subpart D - Prosthetic Devices](#)

**Tympanic membrane contact hearing aid.**

**Sec. 874.3315(b)(5)(v)(C)**

[Subpart F - Therapeutic Devices](#)

**External upper esophageal sphincter compression device.**

**Sec. 874.5900(b)(6)(iii)**

[Subpart F - Therapeutic Devices](#)

**Urethral insert with pump for bladder drainage.**

**Sec. 876.5140(b)(7)(v)**

[Subpart F - Therapeutic Devices](#)

**Rectal control system.**

**Sec. 876.5930(b)(7)(iii)**

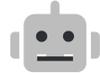
[Subpart F - Therapeutic Devices](#)

**Rectal control system.**

**Sec. 876.5930(b)(7)(iv)**







∨  **Email**

21 CFR §860.3 - Classification of devices intended for human use into one of three regulatory classes: class I, class II, and class III

21 CFR Part 860 - Medical Device Classification Procedures

These are the clauses in 21 CFR 860 that reference benefit vs risk assessment for medical devices. Is there anything

03:55

Give me only 21 CFRs from list above that deal with retina or eye

04:07

1. 21 CFR Part 812 - Investigational Device Exemptions (IDEs): Guidance for Sponsors, Clinical Investigators, and IRBs

2. 21 CFR §812.119 - Changes to an approved investigational device exemption

3. 21 CFR Subpart D - Humanitarian Device Exemptions (HDEs): Guidance for Industry and Food and Drug Administration Staff

4. 21 CFR §860.1 - Scope and Application

5.

04:07

 Reply to GPT-3

