

K183316 Dr J Spinal and Epidural NeedlesAug 12, 2019
255 days to decisionK183316 · Product code: **BSP** · Anesthesiology
Source: <https://www.510kdatabase.net/k183316/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Needle, Conduction, Anesthetic (w/wo Introducer) (BSP) |
| Date received | Nov 30, 2018 |
| Decision date | Aug 12, 2019 |
| Days to decision | 255 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Dr. Japan Co., Ltd. |
| Location | Tokyo, JP |
| Contact | Mitsuko Uchida |
| 510(k) history | 1 submissions · 1 cleared · 2019-2019 |

REGULATORY CONSULTANT

| | |
|-----------------|-------------------------|
| Consulting firm | Smith Associates |
| Contact | Yolanda Smith |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183316/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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