

## Indications for Use

510(k) Number (if known): K110590

Device Name: Carl Zeiss INTRABEAM® System with Needle Applicator

### Indications for Use:

The Needle Applicator set (comprising the Needle Applicator and guide shaft) is indicated for use in combination with the INTRABEAM® System to intraoperatively administer radiation to tissue including irradiation of intracranial tumors.

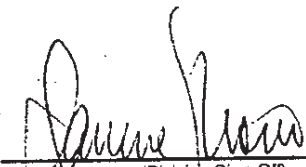
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use       
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K K110590