



Inspection Report

GUIDENT A BOSTON SCIENTIFIC COMPANY

Customer ID: **552**

Certificate: **41-R-0022**

Site: 001

4100 HAMLINE AVENUE NORTH E100

GUIDANT CORPORATION

Type: ROUTINE INSPECTION

Date: Mar-29-2010

ARDEN HILLS, MN 55112

2.31 (d) (1) (viii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.

On 22 April 2009, during the study procedure of protocol 09-038N, an animal (P-1184) died prematurely. During the study one of the study personnel administered medication at a dose in excess of the approved protocol.

The study personnel failed to follow medication dosage administration guidelines established with consultation of the Attending Veterinarian as outlined in the IACUC approved protocol for this animal. This resulted in the animal receiving an overdose of medication and premature death.

The facility has corrected this deficiency by conducting a thorough investigation of this incident. The facility has implemented new training and guidelines for all study personnel to ensure that protocols are followed as written.

Inspection conducted with Attending Veterinarian.

Exit interview conducted with Attending Veterinarian, Manager Research & Technology Center, Director Preclinical Sciences and Quality Manager.

End of Report.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

Mar-29-2010

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Mar-29-2010



Inspection Report

GUIDENT A BOSTON SCIENTIFIC COMPANY

Customer ID: **552**

4133 FERNWOOD AVE

Certificate: **41-R-0022**

Site: 001

GUIDANT CORPORATION

ARDEN HILLS, MN 55112

Type: ROUTINE INSPECTION

Date: Apr-13-2009

No noncompliances identified on this inspection.

Inspection conducted with Attending Veterinarian and Manager Quality/Process Development.

Exit interview conducted with Manager Quality/Process Development, Director Preclinical Services, Manager Research & Technology and Attending Veterinarian.

End of report.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

Apr-13-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Apr-13-2009



Inspection Report

GUIDENT A BOSTON SCIENTIFIC COMPANY

Customer ID: **552**

Certificate: **41-R-0022**

Site: 001

GUIDANT CORPORATION

4100 HAMLIN AVENUE NORTH E100

Type: ROUTINE INSPECTION

ARDEN HILLS, MN 55112

Date: Aug-20-2008

No noncompliances identified on this inspection.

Inspection and exit interview conducted with Quality Manager and Director-Preclinical Service.

End of report.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

Aug-20-2008

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Aug-20-2008



Inspection Report

GUIDENT A BOSTON SCIENTIFIC COMPANY

Customer ID: **552**

Certificate: **41-R-0022**

Site: 002

SURPASS

4100 HAMLINE AVENUE NORTH E100

Type: ROUTINE INSPECTION

Date: Jan-19-2010

ARDEN HILLS, MN 55112

No covered animals at the time of inspection.

Inspection conducted with facility Attending Veterinarian and staff.

End of report.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

Jan-19-2010

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Jan-19-2010



Inspection Report

GUIDENT A BOSTON SCIENTIFIC COMPANY

Customer ID: **552**

4133 FERNWOOD AVE

Certificate: **41-R-0022**

Site: 002

SURPASS

Type: ROUTINE INSPECTION

ARDEN HILLS, MN 55112

Date: Jan-06-2009

No covered animals at the time of inspection.

No noncompliances identified on this inspection.

Inspection conducted with Facility Staff.

End of report.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

Jan-07-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Jan-07-2009



Inspection Report

GUIDENT A BOSTON SCIENTIFIC COMPANY

Customer ID: **552**

Certificate: **41-R-0022**

Site: 002

SURPASS

4100 HAMLIN AVENUE NORTH E100

Type: ROUTINE INSPECTION

ARDEN HILLS, MN 55112

Date: Dec-11-2007

No noncompliances identified on this inspection.

Inspection conducted with Facility Attending Veterinarian.

End of report.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

Dec-14-2007

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Dec-14-2007



Inspection Report

GUIDENT A BOSTON SCIENTIFIC COMPANY

Customer ID: **552**

Certificate: **41-R-0022**

Site: 002

SURPASS

4100 HAMLIN AVENUE NORTH E100

Type: ROUTINE INSPECTION

ARDEN HILLS, MN 55112

Date: Aug-07-2007

No noncompliances identified on this inspection.

Inspection conducted with CEO and Attending Veterinarian of Holding Facility.

End of report.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

Aug-07-2007

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Aug-07-2007



Inspection Report

GUIDENT A BOSTON SCIENTIFIC COMPANY

Customer ID: **552**

Certificate: **41-R-0022**

Site: 004

4100 HAMLINE AVENUE NORTH E100

UNIVERSITY OF MINNESOTA RAR

Type: ROUTINE INSPECTION

Date: Jan-22-2010

ARDEN HILLS, MN 55112

No covered animals at the time of inspection.

No noncompliances identified on this inspection.

Inspection conducted with facility Veterinarian.

End of report.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

Jan-22-2010

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Jan-22-2010



Inspection Report

GUIDENT A BOSTON SCIENTIFIC COMPANY

Customer ID: **552**

Certificate: **41-R-0022**

Site: 004

4100 HAMLINE AVENUE NORTH E100

UNIVERSITY OF MINNESOTA RAR

ARDEN HILLS, MN 55112

Type: ROUTINE INSPECTION

Date: Apr-23-2009

No noncompliances identified on this inspection.

Inspection conducted with facility's Assistant Clinical Specialist.

End of report.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

Apr-24-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Apr-24-2009



Inspection Report

GUIDENT A BOSTON SCIENTIFIC COMPANY

Customer ID: **552**

4133 FERNWOOD AVE

Certificate: **41-R-0022**

Site: 004

UNIVERSITY OF MINNESOTA RAR

ARDEN HILLS, MN 55112

Type: ROUTINE INSPECTION

Date: May-05-2008

No covered animals at the time of inspection.

No noncompliances identified on this inspection.

Inspection conducted with RAR Veterinarian.

End of report.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

May-05-2008

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

May-05-2008